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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION
MDL No. 2804
Case No. 17-md-2804
This document relates to:
Judge Dan Aaron Polster

All Cases

_____/

HIGHLY CONFIDENTIAL
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

The videotaped deposition of JOEL R. SAPER, M.D.,
Taken at 3120 Professional Drive,
Ann Arbor, Michigan,
Commencing at 1:41 p.m.,
Friday, January 11, 2019,
Before Cheryl McDowell, CSR-2662, RPR.

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ALSO PRESENT: MR. MARC MYERS, VIDEOGRAPHER
MR. NEAL ROGERS, VIDEOGRAPHER

TABLE OF CONTENTS

Witness	Page
JOEL R. SAPER, M.D.	
EXAMINATION BY MR. JANUSH:	8
EXAMINATION BY MS. HARTMAN:	118
EXAMINATION BY MR. GABEL:	148

EXHIBITS

Exhibit	Page
SAPER EXHIBIT NO. 1 Curriculum Vitae	9
SAPER EXHIBIT NO. 2 Correspondence dated January 2, 2008	13
SAPER EXHIBIT NO. 3 Correspondence dated July 1, 2008	31
SAPER EXHIBIT NO. 4 Opioid Treatment Guidelines	57
SAPER EXHIBIT NO. 5 New Migraine Study	127
SAPER EXHIBIT NO. 6 The Influence of Pharma and Device Manufacturers on APS and Other PMA'S	75
SAPER EXHIBIT NO. 7 More on The Pain Debate dated March 24, 2010	76

(Exhibits attached to transcript.)

Ann Arbor, Michigan

Friday, January 11, 2019

About 1:41 p.m.

THE VIDEOGRAPHER: We are now on the record. My name is Marc Myers. I'm the videographer for Golkow Litigation Services.

Today's date is January 11th, 2019. The time is now 1:41 p.m. This video deposition is being held in Ann Arbor, Michigan, in the matter of in regards to the National Prescription Opiate Litigation pending in the United States District Court for the Northern District of Ohio, Eastern Division. The deponent is Doctor Joel Saper.

And at this time will the attorneys please introduce themselves for the record and the court reporter, Cheryl McDowell, please swear in the witness.

MR. JANUSH: Evan Janush, Lanier Law Firm, on behalf of the plaintiffs.

MR. MILLICAN: Ian Millican, Lanier Law Firm, on behalf of plaintiffs.

MS. HARTMAN: Ruth Hartman, Baker Hostetler, on behalf of the Endo defendants.

MR. GABEL: Louie Gabel from Jones Day on behalf of Walmart.

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JOEL R. SAPER, M.D.,

having first been duly sworn, was examined and testified on his oath as follows:

MS. HARTMAN: Do you want to get the people on the phone?

MR. JANUSH: People on the phone, can you announce yourselves for the record as well?

MS. BALASTER: This is Mary Balaster representing Amerisource Bergen.

MR. KENNEDY: Sean Kennedy, Ropes & Gray, representing Mallinckrodt.

MR. GHOSH: Pratik Ghosh, Kirkland & Ellis, representing Allergan Finance.

MS. VICARI: Angela Vicari, Arnold & Porter, representing the Endo defendants.

MS. KIM: Mary Kim from Dechert on behalf of the Purdue defendants.

MR. JANUSH: Okay. With that, we'll begin.

EXAMINATION BY MR. JANUSH:

Q. Doctor, hello again.

A. Hi there.

Q. It's nice to have met you a little bit before this deposition began.

And just for the record, you and I have never met before today, is that right?

A. That's correct.

Q. Never spoken before today, is that right?

A. That's right.

(Saper Exhibit No. 1 marked and attached.)

BY MR. JANUSH:

Q. Okay. Doctor, your office provided us with a CV just before this deposition began. I've marked it as Saper Exhibit 1 and put it before you. I've placed it on the Elmo, and I believe counsel all have a copy that are present in this room.

So I just want to start quickly by going through your education and training, your experience as a physician, and your experience treating pain in that order, okay?

So let's start with your education.

A. I went to the University of Wisconsin in Madison and received a degree, Bachelor's degree, in history. I then went to the University of Illinois Medical College in Chicago and received my M.D. degree in 1969, did my internship at Michael Reese Hospital in Chicago, and then came to the University of Michigan in Ann Arbor to study neurology from 1970 to 1973.

In 1973 I was asked to join the faculty of the University of Michigan -- excuse me -- stayed on the faculty until 1978, at which point I resigned to develop the Michigan Head Pain & Neurological Institute which is where we are and received a clinical appointment as a clinical professor of neurology by MSU.

Q. Let's go through your experience as a treating physician now.

A. Received my license in 1969 when I graduated my internship and then became a resident at the University of Michigan and began treating patients and then continued that throughout my stay at the University of Michigan and then have been in this practice, this year marks the fortieth year. So I've been a treating physician for approximately fifty years.

Q. And throughout that fifty-year experience, how many years of experience do you have treating pain?

A. My interest in treating pain began while I was a resident, so that was between '70 and '73, and increased by the time that I left the university which was in 1978. So probably best estimate would be forty-five years.

Q. Okay. And would you consider yourself an expert in

issues concerning pain management?

A. Well, I consider myself experienced. Expert designation is for others to determine.

Q. Okay. When I turn to page two of your CV, I see current, past, current and past key national or state leadership positions.

Can you discuss those current or past leadership positions?

A. Well, briefly, I was president of the American Headache Society from '90 to '92, president of the American Council for Headache Education from '92 to '94, national chair of the Pain Care Coalition from -- what does it say -- 1988 to 2000 and 2004 to 2010, chair, Medical Advisory Board of the Migraine Research Foundation from 2006 to current, and chair, Head and Facial Pain Section, American Academy of Neurology, from '09 to oh '11.

Q. Okay. And the national chair of the Pain Care Coalition, can you describe what that role was?

A. The three major pain societies at the time, American Headache Society -- excuse me -- American Headache Society, American Pain Society, and American Academy of Pain Medicine, joined together to work with legislators and advocacy lawyers during those years, and I was elected to be the chairman of that group,

and that group was called the Pain Care Coalition.

Q. And what did that group do?

A. Well, that group met as frequently as we could and met with a legislative attorney in D.C. During those years I wrote together with Congressman Mike Rogers at the time what became the Pain Care Policy Act signed eventually by -- passed by Congress and signed by I think it was President Clinton. And so we attempted to influence legislation that was to increase access and care of patients in pain.

Let me correct myself. I think it was President Obama that signed that Pain Care Policy Act.

Q. Did there come a point in time when you were asked to be part of a joint American Pain Society, an American Academy of Pain Medicine committee dedicated to drafting new treatment guidelines on the use of opioid products?

A. Yes.

MS. HARTMAN: Objection, form.

BY MR. JANUSH:

Q. And when was that?

A. Well, I don't remember exactly when I was asked to be a member of that committee. It was somewhere around 2008, 2009. It could have been a little

earlier. I'm not sure.

(Saper Exhibit No. 2 marked and attached.)

BY MR. JANUSH:

Q. Okay. I'm going to present to you a document that is marked as Saper Exhibit 2.

MR. JANUSH: Handing copies to opposing counsel.

MR. GABEL: Thank you.

BY MR. JANUSH:

Q. And I'm representing that this is one of the documents that you produced in response to a subpoena.

Does this look familiar to you?

A. Yes, it does.

Q. Okay. What is this document?

A. This document is a letter that I wrote to Doctor Roger Chou who was the administrative chair of the Guideline Committee expressing my concerns at the time.

Q. Okay. Let's take a step back and have you describe for the court what exactly this Guideline Committee was established to do.

A. Well, it was a group of I think ten, fifteen -- I don't remember the exact number -- of well-,

well-known and accomplished health professionals in the pain world, and our charge was to develop guidelines that would help guide the administration and monitoring of patients who were on -- who were placed on opioids for chronic pain.

Q. Was this -- were the guidelines to address patients who had chronic pain generally or more specifically for to address the treatment of non-cancer pain?

MS. HARTMAN: Objection.

THE WITNESS: Well, it was non-cancer chronic pain to be sure.

BY MR. JANUSH:

Q. Do you remember how it was that you got asked to be a member of this joint APS/AAPM committee?

A. I don't recall how that all happened. I imagine that the three presidents of the three contributing organizations, APS, AAPM, and the Headache Society, that one or more of the presidents designated me to be on that committee.

Q. And we began by addressing Exhibit 2, and you noted that this is a letter from you to Doctor Roger Chou.

Tell us more about this letter. Why did you write this letter?

A. Well, the letter is somewhat self-explanatory. I

was expressing concern that certain important aspects of what I think should have been -- what I thought should have been included in the guidelines were not being seriously considered by the committee and that I felt they were critical, and I laid out my essential understanding of what our charge was and why those issues were important.

Q. What were the certain essential concerns that you were seeking to address?

A. Well, there were a lot of good things that the committee attempted to do, but my initial concerns, my concerns at this point that I recall without rereading this entire letter again is was that I felt that physicians who were going to prescribe opioids needed to have certain credentials in not only the treatment of pain but also in the pharmacology, risks and benefits of opioid treatment and that the guideline -- at least the draft guidelines -- did not have much in that credentialing domain.

The other part I felt was essential that patients had been tried when reasonable -- and that's most of the time -- on alternate treatment before jumping to opioids, and I didn't feel that those two areas were covered very well.

Q. You spoke a moment ago about risk/benefit assessment.

Can you explain more what that means and what your concern was regarding a risk/benefit assessment?

A. Well, we all know that opioids are not like other drugs. They have higher risks. They have, of course, the drug dependency potential and interact with other medicines, and so they are high-risk drugs, and there are many of them, different types of opioids, and one has to judge whether the risks of placing a person on opioids balances against the degree of pain and impairment that a person experiences or reports.

Pain is different than other illnesses, than many other illnesses. We can't prove that a person's in pain. We can't prove that a person is not in pain.

And, therefore, the judgment of a physician should be an experienced judgment based upon experience in the field and credentialing perhaps, and those were the issues that were on my mind at the time.

Q. So I'm going to read a specific paragraph and perhaps more than one in this letter and thereafter

ask you a couple of questions regarding the statements that you wrote, okay?

A. That's fine, sure.

Q. Turning to page two, the second paragraph begins: Moreover, in my experience and I trust others', many, if not most, primary care physicians who initially administer chronic opioid therapy -- is that what COT stands for?

A. Yes.

Q. Are not able to discontinue the drugs even when the circumstances warrant discontinuation. Even in the hands of experts, patients are often resistant to discontinuing the drugs despite failure to meet goals of pain control or function. Some bolt to find another willing prescriber or use Internet sources or others when the issue is raised. Considering this and the well-known as well as the not so well-known short- and long-term risks of opioid therapy, I feel we are compelled to develop criteria for initial administration that reflects the realistic risks, dilemmas, and knowledge deficiencies associated with chronic opioid therapy. Failure to do so is giving license to practitioners who are at the very lowest level of understanding of these conditions and the use of this treatment,

ending the quote there.

I want to focus on that paragraph and ask what is it that you were seeking to convey.

MS. HARTMAN: Objection.

BY MR. JANUSH:

Q. If you can explain more -- if you can explain and expand on it for The Court.

MS. HARTMAN: Objection.

THE WITNESS: Opioids as I said carries risks, carry risk, and we had to recognize that the prescriber needed to have training and experience in the field and knowledge of the drugs themselves and that we should not open up the criteria to allow -- we should not write the criteria to allow any physician, any licensed physician, to prescribe these drugs without certain conditions being laid down as criteria.

That's essentially what I was trying to point out given the fact that opioids carry a lot of risks but also have benefits and that the average primary care physician without any special training in pain management or opioid administration should not be given the license to -- with these guidelines, by these guidelines, to administer the drugs.

BY MR. JANUSH:

Q. And when you speak about the notion that opioids carry a lot of risks, what are the risks that you're speaking to?

A. Well, I mean, the risks are many from cognitive impairment to respiratory suppression, and it's not simply the opioid itself. It's the opioid in conjunction with other drugs that can add to the sedative effect, the cognitive effect, the respiratory effect, and there's many other bodily effects, but those are the more important ones, and those are the ones where the greater risk for fatal outcome is likely.

Q. Were you -- how, if at all, were you concerned when writing this paragraph about the abuse potential associated with opioid products?

MS. HARTMAN: Objection.

THE WITNESS: Well, abuse was well known. Years ago a physician that prescribed opioids to a patient without very serious and justifiable cause would likely lose their license. Medical boards around the country would come down on that physician.

I was concerned that the opening of that door and giving license to physicians based upon

very little specific criteria would increase the potential for them to be misused, whether it be for their hallucinatory effects or the sedative effects that many people sought.

We think that some people take opioids not because they have pain, want opioids not because they have pain but because they're quite sedating, quite tranquilizing, and so we had to be sure, and the doctors that were prescribing these drugs had to be trained to be able to discern those distinctions. That was what was on my mind.

BY MR. JANUSH:

Q. How, if at all, were you concerned about the addiction potential related to opioid products when you wrote this paragraph?

MS. HARTMAN: Objection, form.

THE WITNESS: Well, the problem, of course, is that opioids are dependency producing, and that means that the more one takes these drugs, the more one will depend on them and need them, and the dose often is required to escalate to achieve the same effect as the lower dose over time.

And so it was almost that I didn't have to say that to this group of doctors that I was writing to through Doctor Chou. So my concerns in

terms of that paragraph were addressing what I thought I needed to establish with Doctor Chou, and we all understood the addiction potential and dependency potential for the drugs.

BY MR. JANUSH:

Q. When you say we all understood, who is the we that you're speaking to?

A. I'm speaking of the members of that committee.

Q. Moving to the next, very next paragraph, the third paragraph, you wrote, quote: We all appreciate the devastating impact of chronic pain but must be reminded that the urgency of chronic opioid therapy is much less than the urgency of acute pain. It is my view that it is more prudent to take into account many important clinical variables prior to the use of chronic opioid therapy and that it is our responsibility to delineate these and other requirements as part of this project. For example, should prescribing physicians have requisite experience not only with the drugs that are being prescribed, in paren, since they can be fatal, closed paren, but with that particular patient before initiating therapy? Do we really believe that it is appropriate for a primary care physician to administer chronic opioid therapy on a first

visit with a painful patient? Our current work product and guidelines would support that practice. I do not. End quote.

How was that statement received by Doctor Roger Chou?

A. Well, I'm not sure that I know exactly how Roger received that communication. I know that I believe -- I don't have a calendar of my activities. I believe that after he received this, he shared the letter with others on the committee, and what resulted from that is a Saturday morning conference call that I and several other members of the committee were on -- I think Roger was on it as well -- for us to discuss these various issues.

So I don't specifically know what Doctor Chou's -- Doctor Chou actually played a more administrative role than a clinical directive role. So I think he just passed this on to the committee.

Q. Okay. Before we get to that Saturday call and discuss that a bit, I'd like to go on to the next paragraph. You wrote, quote: That all patients do not have access to specialists or centers should not in and of itself deter us from developing appropriate guidelines for the many who do. Exceptions will obviously have to be made, but our

standard criteria must be responsible and appropriate, rigorous, and we must presume that they will apply to the weakest prescribing links in the clinical chain. Many of us presume that they will apply to the weakest -- many of us have seen -- excuse me -- the consequences when chronic opioid therapy is inappropriately and unwisely administered or when unacceptably sustained availability occurs in the individual who should not have been administered the drugs in the first place, quote.

What were you conveying here?

MS. HARTMAN: Objection.

THE WITNESS: Well, one of the arguments against my requests was that not all patients have access to specialists or advanced-trained individuals in the treatment of pain such as those perhaps in rural areas of the country.

So I was acknowledging that, yes, we may have to make some exceptions in some cases but that the general set of guidelines should not be watered down so to speak to accommodate that piece rather than setting up the high bar for protection of the patient. So that's what I meant by that part of it.

And then the latter part of it of that paragraph was essentially to state that we had to be

concerned because when people are maintained on these drugs for very long periods of time, it becomes very difficult to take them off of it, and we all know what the consequences of that is or are.

BY MR. JANUSH:

Q. And what are the consequences of that --

MR. GABEL: Objection, form.

BY MR. JANUSH:

Q. -- that you are referring to when people are on the drug for long periods of time and it becomes difficult to take them off of the drug?

A. Well, even if the reason that their pain improves independent of the drugs or even if it hasn't improved but if the physician knows or feels that it's time for the patient to come off or if the patient is multisourcing and not taking the drugs as prescribed, then there are consequences to that, and the physician may well change their mind.

But then with drugs such as these, the patient can't just be called in and say, okay, John, we're going to take away your Percocet or your oxycodone because it's not that simple with opioids. It's not like an antidepressant. It's not like a beta blocker or some of the other drugs that we have access to.

And so we have to be very careful in establishing criteria for usage that embodies the recognition that this is much more complicated than just prescribing a drug to an individual, having the person come back and say, okay, let's do something else. It's not that simple.

Q. When you say that an opioid product is not like a beta blocker as an example, what is it that you are referring to?

A. Well, I'm referring to the dependency development. Let's use the word addiction, although addiction has other implications, but, so the dependency or addiction potential, the reduction of respiratory and sometimes cardiovascular function, and the interaction, sedative interaction with many other drugs that a patient in pain might be administered at the very same time. Rarely is a patient solely placed on an opioid.

But I want to just caveat and say there is a place for opioids in the treatment of pain, and I was specifically addressing how should we write criteria to protect the patient from these medications and yet be available to those who really needed it and be monitored carefully when they were taking it.

Q. In the last paragraph on this page, this second page of Exhibit 2, you wrote, quote: My views may not be shared by other members of the committee, but increasing numbers of physicians in this country are coming to believe that the opioid door has been opened too widely. Some are arguing to return to an earlier time when restrictions were unreasonable and unfounded. I do not share the view that we should return to those days. However, considering regulatory and clinical realities, I do believe that we are compelled to develop responsible guidelines for both initial administration and continuing treatment. This is both our opportunity and responsibility, quote.

The first sentence of that quote addressed that your views may not be shared by other members of the committee.

Can you describe what you were feeling at the time or observing at the time with respect to whether you were an outlier within this committee?

A. Well, I knew that I was. I had been at the last meeting that we had had. I can't remember where it was held, but there were probably fifteen people there on the committee and Doctor Chou, and as we discussed these issues, it became clear to me that I

was in the minority, stark minority, and so that's the basis of me saying the views may not be shared by other people on the committee.

You know, I could -- at this point in the saga of these events, I was simply trying to point out to Doctor Chou and the other members of the committee that we had a responsibility. If we wanted to protect the ability of patients to receive opioids, when appropriate, then we had to establish rigorous guidelines for that protection to be sustained.

And that was, that was the whole ballgame for me, setting up appropriate criteria for who should administer rather than just anybody, any doctor with a license, and that we had ways of watching and monitoring and setting criteria for the clinical course of that patient before opioids were established.

Q. You ended your letter by stating, quote: I deeply regret that my lengthy letter comes so late in the game, but it is not too late. I equally regret and apologize to all of the members of the committee for my unavailability at several of the meetings or conferences, quote.

What did you mean when you wrote that you

regretted that your lengthy letter comes so late in the game but it is not too late?

A. Well, I don't remember exactly what prevented me from attending some of the other meetings. Some were conference calls. I was very professionally busy at that particular time in my life, and I was still holding various positions in organizations and teaching quite a bit.

So I couldn't attend all the meetings, and I would read the minutes, I'd read what was sent to me, and so that was just acknowledging that I had not been able to be present at all the meetings.

Q. And so when you were writing but it is not too late, were you referring to not too late with respect to the opioid issues in America, or were you referring to it's not too late with respect to the time line of the committee's work?

A. Time line of --

MS. HARTMAN: Objection.

THE WITNESS: I'm sorry.

MS. HARTMAN: You can answer.

THE WITNESS: Time line of the committee's work.

BY MR. JANUSH:

Q. Okay.

A. I don't think that at that point the guidelines had been completed. They had not been published for sure, and so that's what I was referring to.
Q. Okay. And earlier you had testified about the fact that there was a Saturday morning call-in, a conference call meeting over your letter after Doctor Chou sent it around to other committee members, is that right?
A. I'm assuming that that was the basis of that, that meeting. Certainly we discussed my views at that meeting, but I'm not sure that it was prompted solely by my letter. Maybe it was. I don't know that.
Q. Do you remember any of the participants that were on the call at that meeting?
A. I think -- I certainly don't have full recollection. I think that Perry Fine was on the phone at the time, but, honestly, I don't, I don't remember. There was about four or five people on the call. That's all, four or five people.
Q. And do you have any specific recollections of the content of the discussion of that Saturday conference call?
A. Just in general. They didn't agree with me. They tried to -- politely and respectfully to dissuade me

from my views. They felt that if we put too high a bar for opioid treatment, either professional training or credentialing or too big of a step that a patient would have to take before opioids could be administered meaning where along the algorithm of treatment do opioids belong that it would prevent some people who needed opioids from getting opioids, and that was their view, that that was their concern as expressed to me.

I'm vaguely remembering this, so I don't want to misquote anybody.

Q. Following your transmission of this letter on January 2nd in 2008 and in between or, stated differently, in between January 2nd, 2008, and July 1, 2008, do you recall what work you -- what involvement you had with this committee?

A. I don't recall that I had much involvement with the committee at all which is not to say that I might not have talked to some people. Maybe I even talked to Roger Chou.

I know I had a conversation at one point with Doctor Jane Ballantyne who is a member of that committee and at least to my recollection was the one other member whose sentiments closely parallelled mine, although not necessarily as

strongly as I felt about those issues, and I do remember a brief discussion I had with her at a medical meeting that we both attended.

But I honestly don't recall much work with the committee between that time and my resignation letter.

Q. Were drafts of the policy guidelines sent around to you as a committee member between January 2nd, 2008, and July 1, 2008?

A. I believe that they were. I don't remember that specifically, but I think that it was the absence of any change at that point fundamentally in the guidelines that prompted me to write my letter.

Q. Okay.

A. My next letter.

(Saper Exhibit No. 3 marked and attached.)

BY MR. JANUSH:

Q. Now we're going to get into that next letter. I'm going to hand to you what's been marked as Saper Exhibit 3.

MR. JANUSH: Handing a copy to opposing counsel.

MS. HARTMAN: Thank you.

MR. JANUSH: Okay. I'll put it up on the

Elmo to the best that I can.

BY MR. JANUSH:

Q. Is this the resignation letter that has been marked as Exhibit 3 that you have just testified about?

A. Yes.

Q. Okay. And looking at the top of Exhibit 3, it's addressed to a Judith Paise, Ph.D., R.N., president of APS.

Is that president of American Pain Society?

A. Yes.

Q. And it's also addressed to Doctor B. Todd Sitzman, the president of the AAPM.

And that's the president of the American Academy of Pain Medicine?

A. Correct.

Q. Okay. And why did you send this letter on July 1, 2008?

A. Well, they were the president, the current presidents of the two organizations that had sponsored the meetings, and one or both of them had something to do with my appointment to the committee, although I think Doctor Sitzman had just been elected president, so it might have been the previous president.

But they were the current presidents of the organizations, and I felt that I needed to let them know how I felt and sort of publicly state the reasons why I wanted to resign from the committee.

Q. Okay. So we'll start with this quote in the middle of the first paragraph. You write: Nonetheless, I feel compelled to separate myself from the committee and express my concerns to you. It would not take such a -- forgive me. I would not take such an unconventional step were it not that I consider this issue of significant importance and a matter of public safety.

What was the issue that you considered of significant importance and a matter of public safety?

A. Well, it was the issues we've already discussed, the concern that we needed to establish a credentialing pathway for doctors to be able to prescribe COT.

I do want to just emphasize if I may that we were talking about chronic administration of opioids. We are not talking about the use of opioids for a broken bone or postoperative treatment of opioids. These were cases where we were going to put people on opioids for weeks, months, or years, and that was the issue I was addressing.

I was not, I was not bothered by the ability of a primary care or any other physician, licensed physician, who would give a short-term course of opioids for acute pain. So I wanted to make that point.

And so I was quite concerned that without credentialed and criteria for experience with chronic pain, nonmalignant chronic pain, and in the safety and pharmacology of opioids that those would lead to serious public safety issues.

Q. And moving on to the last paragraph on the page with subparts A, B, we skip C and go to D.

A. Yeah.

Q. Typo, right?

A. I noticed that as I was preparing for this deposition.

Q. Okay.

A. So I embarrassingly apologize --

Q. No.

A. -- for leaving out C.

Q. I'm just being accurate so that I'm quoting it correctly.

These issues here, A, B, and D, do these issues concerning, A, physician competence to evaluate chronic pain and determine the appropriate

treatment and physician knowledge to prescribe opioids safely, is that one of the issues that you've previously been testifying about?

A. Yes, it is.

Q. Okay. And then moving to B or the second issue, you wrote the importance of effective and responsible monitoring of usage and treatment efficacy, making certain that the treatment goals are achieved.

That's something that you were concerned about with respect to the drafting of these guidelines, is that right?

A. Yes, it is.

Q. Okay. And then the third issue you wrote: Physician willingness to discontinue opioids when appropriate, is that right?

A. Yes.

Q. And was that something that also you were concerned about related to the drafting of the chronic opioid guidelines by the APS and AAPM Joint Committee?

A. You know, it's a long time ago, and I don't remember where in the guideline development some of these issues were.

But I did not feel that there was enough attention paid to how to discontinue, how a doctor would prescribe opioids but then were not -- was not

trained, prepared, or taught even informally how to go about taking a person off those drugs. That's what the third, the D was.

Probably instead of the word willingness, I probably should have used willingness or ability to discontinue the opioids, but there was a general assumption at the time that we would -- that patients would be put on opioids, and then if they had to come off, that generally wasn't going to be your average primary care doctor who the guidelines were giving license to giving opioids chronically, again, distinguishing that from acutely, and he would have to be sent -- the patient would have to be sent to a substance program or to a substance abuse treating physician.

So that was different than any other medicine that a doctor would give which is if you're not doing well or you have a side effect, then the doctor takes you off the drug, gives you something else. So I was -- these concerns were embodied in all those considerations.

Q. Okay. I'm going to move to the second page of your letter, and you start at the top by saying: In short, a well-founded concept of risk management must be integrated into the guidelines.

What were you referring to when you talked about a well-founded concept of risk management or wrote about?

A. When people were on these drugs, we had to make certain that, one, they were cognitively functioning with clinical issues, cognitively functioning well, that we were aware of all the other drugs that might be administered by any other doctor in their world, you know, for some other problem that would have to be -- that would interact with the opioids. So that was the clinical risk issues.

Then there were the issues of abuse, multisourcing, personal dose adjustments by the patient, and we needed to develop concepts of urinary drug screening and other ways to monitor the patient and that we needed to establish contracts for mutual agreement on how that patient was going to be monitored and their responsibility, how often were they going to see the doctor, how frequently were urinary drug screens going to be or any drug screens going to be done, that one pharmacy would be the administering pharmacy rather than anywhere in town, ways to protect against what we had learned from experience or those of us who had learned from experience were aware of what the risks were in

administering opioids.

Q. When you speak about one pharmacy being the administering pharmacy rather than a patient perhaps filling multiple prescriptions around town, are you referring to the concept of doctor shopping or pharmacy shopping?

MS. HARTMAN: Objection.

THE WITNESS: Yes. We didn't have the monitoring programs that we have today at that time. They were in the early phases. There was talk. In fact, the Pain Care Coalition that we talked about earlier, we were talking about, you know, the various pharmacy-monitoring programs.

So one way to protect a patient and keep an eye on what was happening, recognizing reality, I guess I would emphasize what we all knew as reality with opioids was to one prescribing doctor, one dispensing pharmacy, and that patients would agree to that, and that was a way to protect.

BY MR. JANUSH:

Q. I'm going to move forward just a little bit into the third paragraph. It's actually the second paragraph, but it begins with with some minor exception, and it states in the second sentence: The guidelines in their current form principally

focus on and emphasize the post-prescribing period and not the pretreatment period. And you wrote: By failing to establish pretreatment competence expectations, the guidelines either assume competence or reflect the view that no special knowledge or experience is required to effectively and safely carry out the assessment and treatment of chronic pain patients, quote.

I'm actually going to not end it there. I'm going to read one more sentence. You wrote: I believe that most reasonable authorities would find this -- find that indefensible.

Is this the concern you were speaking to in your earlier letter of January 2nd, 2008, where you were also addressing competence expectations?

A. Yes.

Q. And you continued by saying: In any case, it is a cause of serious concern for me and others. The U.S. has a serious prescription drug and abuse problem. In many instances there appears to be a direct linkage between easy to excessive availability, ineffective assessment, unsafe prescribing patterns, and/or ineffective monitoring. The guidelines do address monitoring, but not the pretreatment willingness or capability of physicians

to undertake monitoring.

Can you expand on that to explain the concern about the guidelines not addressing the pretreatment willingness or capability of physicians to undertake monitoring?

A. Yes. One of my principal concerns was that in addition to lacking any credential criteria for who should and could prescribe opioids chronically, again, emphasizing we're not talking about acute treatment but chronically, there was also a failure at that time to delineate the monitoring responsibility of that physician and that that physician had to take upon him- or herself the responsibility of monitoring which is not quite the same as monitoring for a dose of antihistamine that you prescribe or a beta blocker or an antidepressant even.

There's a much more rigorous requirement with opioids. There should have been. There wasn't. So that's what I'm stressing --

Q. And in the --

A. -- at that time.

Now, I should add that when the published criteria, when the published guidelines came out, I was pleased to see that there was a little bit more

in that direction in several of these issues -- not all of them -- that I was raising. But at the time, they weren't there.

Q. And we'll get there in a bit.

You next wrote: Despite my efforts during the development process to influence these guidelines through the committee structure, my efforts were rejected.

Earlier we were talking about that call you had after the January 2nd, 2008, letter that you sent, and you indicated that you were in the minority.

Do you remember that?

A. Yes.

Q. How, if at all, did committee members or committee leaders express to you that your efforts to influence the guidelines were rejected?

A. I don't think anybody ever except for that meeting where I clearly hadn't changed anybody's opinion that I was aware of, nor mine, I don't remember anybody at some point coming up to me and to say, well, we're rejecting your thing. There was just basically nothing said.

I think at some point I must have seen the next rendition of the guidelines, and then I

understood that those ideas had not been adopted.

Q. And moving on to the very next paragraph, you wrote: The liberalization of opioid use for chronic non-cancer pain has brought both good and bad. There are many patients today who are living lives that have been salvaged and made more comfortable, if not productive and joyful, because of the availability and proper administration of opioids for what several years ago would have been considered a prohibited use. But it must also be acknowledged that liberalization has brought considerable harm, also, and it is to this point that my strong feelings are directed, quote.

What is the considerable harm that liberalization of opioid drugs has brought as of writing this letter on July 1, 2008?

A. Well, sorry. I think we were beginning to see the deaths that were occurring that we believed were attributed to the opioids. We certainly saw drug misuse, multisourcing. We saw some violence and burglaries to obtain drugs.

And so I remember saying at one of the lectures I gave, I don't remember anybody ever breaking into a drug store to get a beta blocker, you know. I mean, it created a behavior that we had

not seen before but we're beginning to see in all this, and so the death risks, the criminal behavior, the substance abuse issues, all of these things we were beginning to see.

Q. Okay. And I'm going to turn the page to page three of your letter. I'm going to begin at the paragraph starting with finally right here. And you wrote: Finally, I must point out another important concern. It is reasonable to assume that the guidelines project has either directly or indirectly been supported by the opioid industry. The sponsoring organizations have received a large amount of funding from the opioid manufacturers over the past decade. Many members of the committee have personally received sizable funding from the opioid industry as well. Congress currently is intently interested in both the prescription drug problem and how physicians and professional organizations are influenced by the flow of dollars to them from the pharmaceutical industry and how this influences treatment policy, guidelines development, and teaching, quote.

Can you elaborate on what you were writing in July of 2008 concerning the sponsoring organizations having received a large amount of

funding from the opioid manufacturers over the past decade?

A. Well, it was my -- I had been on the board of APS and AAPM. At one time I was -- they tried to recruit me to become a president of AAPM, but I couldn't handle it with all the other stuff I was doing.

And so I was aware that these organizations, like most medical organizations, were being supported by companies that had an interest in the products that that group of doctors would use, would prescribe. And when we put the -- when the committee was put together, the Guideline Committee, it became apparent -- I can't remember the moment I heard this -- that grants had been received by APS and AAPM from the opioid manufacturers, Pharma, for this committee.

In fact, and I must say that was not a lot different than most medical organizations would handle things. In other words, they would go to industry or industry would go to them and say how would -- we'd like to support a particular project and ask for a grant, and then the grants were granted very often, not always I know.

But, so that was what I was referring to,

that this was a committee established, that people on this committee were known to work closely with these drug companies and give talks, what was common practice in medicine, still is, and that the companies were heavily investing in the programs and projects of these organizations.

Q. Were you concerned when writing this paragraph about the potential for the pharmaceutical industry or the pharmaceutical manufacturers that produce opioid products to influence treatment policy?

MS. HARTMAN: Objection.

THE WITNESS: Yes, I was, because I will say again, opioids are different, and opioids are not like some of the other drugs which have a whole different profile and safety margin.

Not that it makes it better one way or the other, but the risk is that advocacy for those drugs has to be based on medical common sense independent of the financial flow of dollars, and it was my growing fear that that was not the case in the case of these guidelines and programming within the various organizations.

BY MR. JANUSH:

Q. You had also addressed as you spoke to moments ago that many members of the committee had also received

funding from the opioid industry as well, did you not?

A. I did.

Q. And, actually, in your letter you wrote: Many members of the committee have personally received sizable funding from the opioid industry as well.

As you sit here today, do you recall any specific examples of members of the committee who received funding from opioid industry?

MR. GABEL: Objection, form.

THE WITNESS: I think only that it was known amongst us that several of the people were very strong advocates for these opioids and were on the lecture circuits advocating for these opioids. Those are paid responsibilities. They were on advisory boards.

Again, I will say that that is not different than it is in the non-opioid domain of medical education. The drug companies tend to do most of the supporting of medical education. That's true.

I felt -- still do -- that with opioids, they were penetrated in a much more intense way and that we were dealing with a much more potentially dangerous product that needed to be handled much

more independently of people with a vested commercial interest.

BY MR. JANUSH:

Q. And in addition to addressing the specific people that served on the committee and whether they individually received funding, did some of these people that served on the committee work for universities that you know received funding or grants from opioid manufacturers while working on this committee?

MS. HARTMAN: Objection, form.

THE WITNESS: I can only assume that that was the case, but I don't know that. At this point I don't recall those specifics.

BY MR. JANUSH:

Q. Do you recall one way or the other whether the University of Wisconsin Pain and Policy Study Group was receiving grants from opioid manufacturers while working on this joint APS and AAPM committee?

MS. HARTMAN: Objection.

THE WITNESS: I'll tell you what I do recall, but I'll give you what I remember. There were, there were two professionals at the University of Wisconsin that I remember. One was June Dahl, D-A-H-L, and another one David Jorensen. To my

recollection they were both in the School of Social Work, they were clinical people, and that they had a project supported it's my understanding because as I think back, and I have to qualify that by saying I'm not one hundred percent certain, but it's my understanding as I recall it that that was support, that their project which was to go to the medical boards around the country and attempt to change the board's position on doctors that prescribe opioids, and that was an initiative that was my understanding as I recall it was supported by some of the opioid industry.

I don't want to lump everybody together. I don't know if it was one company or ten companies. I just -- that was the common knowledge at the time.

BY MR. JANUSH:

Q. And when you say that June Dahl and Mr. Jorensen were going around the country to various medical boards, what were they seeking precisely to do as you understand it?

A. The project that they had was to advocate a more liberal attitude towards -- toward doctors who prescribed opioids to their patients with pain and that they were trying to present data that would change the nature of things which was to be quite

restrictive, boards to be very restrictive in allowing physicians to treat nonmalignant pain with opioids at that time.

Q. That flows into what my next question concerns which is the paragraph in the middle of the page three of your July 1, 2008, letter where you state: The zeal to aggressively treat pain may have placed our responsibility to, quote, first do no harm, quote, in second position. In my view the guidelines have set the bar so low for initial administration by any physician who has a medical license and DEA number that the guidelines will, in fact, encourage use by those who are unprepared to carry out the task responsibly and safely, period, quote.

Is this, again, referring to the notion that any doctor would be in a position to prescribe opioids and that is unsafe?

MS. HARTMAN: Objection.

THE WITNESS: Well, potentially unsafe, yeah. I mean, it was referring to essentially the fact that we have -- we took upon ourselves to advocate for the need to more aggressively treat pain. I support that. I supported it then, support it now. And one of the means of treating pain was the use of opioids.

And I felt that in the case of opioids that there was such strong and often one-sided advocacy for prompting the use of opioids through teaching and through courses and through guidelines that we were forgetting that while treating pain is our responsibility, not doing any harm is our first responsibility, and that was the point I was trying to make.

BY MR. JANUSH:

Q. And in the following paragraph which you -- is really only one sentence that's bolded by you, you wrote: Such guidelines developed with the support of industry and by many who have been personally paid large sums of -- large sums by industry create a nexus that will not be ignored.

What is the nexus that will not be ignored that you were referring to here?

A. Well, the entire initiative to use opioids in an aggressive way to treat pain and that the teachers and the instructors who are giving courses on how to do that at major pain meetings were people that were also being paid for various other tasks by the drug industry. It was a conflict, and that's what I -- the nexus was a conflict.

Q. Okay. And in the following paragraph you address:

In short, the absence of pretreatment competence expectations from this scholarly group of physicians and other professionals suggests that nothing special is necessary. I believe this is a dangerous position given the current circumstances. We should know better. Chronic pain does not compel an emergency response as might be argued, might be argued by the case of acute pain. Diligent training and competence should not be prerequisite --

A. Should be.

Q. Sorry. Should be -- thank you -- prerequisites to the chronic administration of opioid therapy. These guidelines do not advance this principle.

Can you elaborate on this paragraph further and explain the core of what you were addressing regarding the notion that chronic pain does not compel an emergency response?

A. Again, distinguishing that acute pain, one has to respond quickly, and like any other emergency situation or urgent situation in health care, you know, you sometimes have to bridge the guidelines, bridge the behavior to get to the urgent problem. But we didn't have that urgency in chronic pain. There needed to be time taken to learn about the patient.

For example, one of the things that I didn't think that I said somewhere along the line was that one shouldn't be giving opioids to the patient who they just met because we don't know that patient yet. We haven't had a chance, haven't had a chance to read all of the background material or past medical records of the patients who come to see us, and we don't have a sense of that patient's accuracy or honesty.

Forget we don't have an x-ray to put up on the screen to say, oh, look at that fractured bone. We don't have an anatomical correlate that can validate the presence of severe pain.

So we have to use good judgment and experienced judgment to determine what should be given to whom, and I didn't think that that was being addressed in these guidelines and that diligent training and competence should be prerequisites. There wasn't a rush to prescribe today when you see a patient.

Q. And you concluded your letter by writing, quote: Deaths and harms have come to many patients prescribed opioids. The media knows it. Government and regulatory agencies know it. Our guidelines must do a better job of addressing it, exclamation

point.

How did people who received this resignation letter respond to this paragraph, if at all?

MS. HARTMAN: Objection.

THE WITNESS: I don't remember much of a response to this letter. Actually, I think Todd Sitzman, the new president of APS, did come up to me and thanked me for sending the letter. We didn't have much of a conversation, but he didn't have to have. He looked me in the eyes and he said thank you for the letter. So I knew that that was a meaningful connection.

I don't remember receiving much else from anybody that I was interacting with. Now, it may have occurred. I just don't remember it.

BY MR. JANUSH:

Q. After getting -- after you transmitted this resignation letter on July 1, 2008, who, if any, contacted you to talk you out of your resignation from the committee?

A. Nobody.

Q. Did you ever speak to anybody about that fact, anybody on the committee about that fact?

A. That nobody tried to talk me out of it?

Q. Yeah.
A. I don't recall talking to anybody about changing my views or going back on the committee.
Q. One can have a dissenting view as a member of a committee and theoretically still stay on the committee and express their dissenting view, is that right?
A. Yes.
Q. In this case, however, when you left the committee, the outcome of that was unanimity on the committee, wasn't it?
MS. HARTMAN: Objection.
THE WITNESS: Well, nobody -- I'm sorry. Nobody asked me to leave. I mean, I wasn't asked to leave the committee.
BY MR. JANUSH:
Q. I'm not addressing that. I'm not addressing that.
I'm addressing the notion that did any potential exist for you to stay on the committee, express your views, and ask for a dissenting note within the guidelines?
MS. HARTMAN: Objection.
THE WITNESS: No, no, I didn't ask for that. I didn't want my name associated with those guidelines, and that's what prompted me to write

this letter.

Nobody asked me to leave, nor did anyone ask me to stay, and I don't actually know how many members of the committee saw this letter. I sent this to the two presidents. I didn't send it to everybody on the committee.

And so I don't know whether there might have been a different response if everybody had received the letter. I thought it was my duty to write it to the two presidents.

BY MR. JANUSH:

Q. Let's see if turning the page refreshes your recollection on that. I see a last --

A. Oh, I did send it to other people. I'm sorry.

Q. I see that it was sent to Rollin Gallagher, a doctor, Catherine Underwood, the executive director of APS, a doctor named Philipp Lippe from San Jose, California, Phil Saigh, the executive director of AAPM, Richard Rosenquist, M.D., Roger Chou who we spoke about earlier, Doctor Jane Ballantyne, Doctor Fred Sheftell, and Doctor David Dodick from the Mayo Clinic.

I don't see more than that on the CC list, and it certainly looks like there were ten other pages once potentially attached to this letter

by virtue of the five of fifteen at the top of the paper.

Do you see that?

A. I do, and I'm very embarrassed that I didn't realize that I must have sent this letter to many more people. These are all members of the various organizations. Some are presidents, like Doctor Sheftell was the president of the Headache Society at the time. Doctor Dodick was the incoming president of the Headache Society. Doctor Rosenquist was the head of the American Anesthesiological Society. Everybody else, their title is pretty evident.

So I guess I have to correct myself and say, yes, I sent this letter on to other people and that I don't recall anybody attempting to change my mind which was your initial question on this regard.

Q. And by change your mind, I'm not speaking to change your mind on your belief system. I'm talking about change your mind on resigning from the committee.

A. That is correct. I don't recall. I mean, there might have been somebody that asked me to reconsider, but I do not remember that.

Q. Okay. That would have been a pretty poignant thing to remember, wouldn't it?

MS. HARTMAN: Objection.

THE WITNESS: Yes.

MS. VICARI: Objection to form.

BY MR. JANUSH:

Q. Would that have been a poignant thing to remember?

A. If somebody would have asked me to stay?

Q. Yes.

A. I think I probably would have remembered it, but, you know, it's a long time ago.

(Saper Exhibit No. 4 marked and attached.)

BY MR. JANUSH:

Q. I'm going to move on to another exhibit that we've marked Saper Exhibit 4. This is the Opioid Treatment Guidelines that we've been speaking about.

MR. JANUSH: Counsel, here are copies.

BY MR. JANUSH:

Q. Now, you in your production only produced a portion of the total treatment guidelines, so we found this from within the American Pain Society's third-party production, but it's also available publicly on the worldwide web, and I could have easily printed that out just the same.

But I just wanted to make it clear to you as the witness that this is not the copy you gave,

you provided in response to the subpoena.

A. If I may respond to that, the copy that I provided you is the copy that we had in the file.

Q. Right. Understood.

A. And I think on the Internet, the first several pages were there, and then you had to go to another something to get the rest of it, and I think that for the file, we didn't have that.

Q. Understood. Not faulting you in any way. Just wanted for the record it to be clear why you have the complete set before you --

A. Sure.

Q. -- or what I believe to be the complete set.

A. Right.

Q. Let's see. The first question, is this the Opioid Treatment Guidelines reflective of the committee that you originally served on before resigning?

A. Yes, it is.

Q. Okay. And do you recognize the names at the top of the page? Why don't you read them into the record and then tell us if all of these folks were people who served with you on that committee before you resigned.

A. Well, I don't remember everybody.

Q. Okay.

A. But I do remember many. So Roger Chou I do, Gilbert Fanciullo I do, Perry Fine, Jeremy Adler. I'm not so sure I remember that. Jane Ballantyne, yes. Pamela Davies, no. Marilee Donovan, yes. David Fishbain, yes. Kathy Foley, I don't think she was at the meetings, but, yes, I remember. She might have been, but, yes. I know her. Jeffrey Fudin, no. Aaron Gilson, I don't recall that name, nor Alexander Kelter. Alexander Mauskop, yes. Patrick O'Connor, I don't remember. David Passik, Steven Passik, yes. Gavril Paternak, yes. Russell Portnoy, yes. Ben Rich, I don't recall that.

Hold on one second. Let me just try to refresh myself.

No, I don't remember that person. Richard Roberts, I don't remember that person. Knox Todd, I'm not sure I remember that. Christine Miaskowski, yes.

Q. Okay. And turning to the --

A. Excuse me one second. If I can correct myself, I do remember I think Ben Rich, and he was from the University of -- no, wait a minute. University of Wisconsin was nineteen -- Richard Roberts, I do remember Richard Roberts.

Q. And I'm going to turn to the second page, and I'm

going to address, follow my highlighting if you will right here at the American Pain Society.

A. Okay.

Q. And the second column, it says: The American Pain Society, APS, in partnership with the American Academy of Pain Medicine, AAPM, commissioned a multidisciplinary panel to develop evidence-based guidelines on chronic opioid therapy for adults with CNCP.

Does that stand for chronic non-cancer pain?

A. Yes.

Q. These recommendations are based on a systematic evidence review, also commissioned by the APS and AAPM.

Do you see that?

A. Yes.

Q. And what was to your knowledge, if you recall, what the systematic evidence review was?

A. Well, it wasn't as rigorous as I would have wanted it to be. There wasn't a lot of data on some of the key issues. There was an attempt made I believe to make this as rigorous as they could make it. I think that Roger Chou who was sort of in charge of all this, I do think he was erudite and scholarly

in his attempt to put together a defensible document.

So that's what that means, that they attempted to do a well-documented and evidence-based issue, but there's not evidence for everything that the guidelines address. There just isn't evidence.

Q. And when we speak to evidence based, was it literature that was being reviewed, scientific literature or published medical literature that was being reviewed and assessed by the committee and scored based on whether the literature -- how the literature ranked in terms of unreliable at the bottom, moderate in the middle, and highly reliable at the top?

A. Well, evidence is --

MS. HARTMAN: Objection.

THE WITNESS: I'm sorry. Evidence is ranked in general when we do evidence review, and it is ranked according to the rigor of the study that developed that evidence. If it was a double-blind controlled, placebo-controlled, double-blind, placebo-controlled study, a randomized trial, if it was an open label, if it was just case reports, letters to the editor, things that are in the literature.

So those are ranked in terms of their scholarly intensity and validity. I was not part of the process for that literature review, and so I can't really speak in detail.

BY MR. JANUSH:

Q. So let me focus your attention to page three of this. Actually, we'll start with funding and conflicts of interest. At funding and conflicts of interest, it states: Funding for the guideline was provided by the APS, period.

Are you aware of whether there was ever any disclosure as to who funded the APS itself for the creation of this guideline?

MS. HARTMAN: Objection.

THE WITNESS: Well, it certainly doesn't acknowledge it, but it was my understanding at the time that that funding was coming from various of the manufacturers of opioids.

BY MR. JANUSH:

Q. Okay. And initially I addressed --

A. And that might have been a grant to the organization. I'm not suggesting that there was a direct funding to the committee. It was coming from APS or AAPM, and I'm assuming that it was through a grant from the manufacturers to the organization.

Q. Okay. Earlier I addressed moments ago the concept of the evidence review, and here we have a section called evidence review, and it states that: Literature searches were conducted through November 2007. Investigators reviewed eight thousand thirty-four abstracts from searches for systematic reviews and primary studies from multiple electronic databases, reference lists of relevant articles, and suggestions from expert reviewers, a total of fourteen systematic reviews and fifty-seven primary studies, not included in previously published systematic reviews, were included in the evidence report.

Do you see that?

A. Yes.

Q. Do you recall how many recommendations were ultimately made following the review of this so-called evidence?

MS. HARTMAN: Objection, form.

THE WITNESS: I don't remember much of this at all.

BY MR. JANUSH:

Q. Okay.

A. I regret that which, again, is not to say that it didn't occur the way it's described. But I don't

recall being subjected to that data, nor reviewing it in any way. At least I don't recall.

MR. JANUSH: Off the record for a moment.

THE VIDEOGRAPHER: Going off the record at 3:09 p.m.

(Off the record at 3:09 p.m.)

(Back on the record at 3:19 p.m.)

THE VIDEOGRAPHER: We're back on the record at 3:19 p.m.

BY MR. JANUSH:

Q. Earlier I was speaking about the quality of evidence, so I'm going to have you flip to the page that is marked in the bottom right corner APS-MDL, at least four or five zeros, and then it's 162, and it's Appendix 2.

Do you see that?

A. Yes.

Q. All right. This is the grading evidence and recommendations concerning the grading methods that are -- were utilized that I was referring to earlier in evaluating all of the literature and evidence that was looked at for this policy guidelines that was implemented.

Do you see that?

A. Yes, I do.

Q. Okay. And there are three different ranks. High-quality evidence, and that states that it's evidence includes consistent results from well-designed, well-controlled, well-conducted studies in representative populations that directly assess effects on health outcomes, at least two consistent higher-quality randomized controlled trials, or multiple, consistent observational studies with no significant methodological flaws showing large effects.

Do you see that?

A. Yes.

Q. And then there's moderate quality as the middle intermediary. Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, size, or consistency of included studies, generalizability to routine practice or indirect nature of the evidence on health outcomes, at least one higher-quality trial with less than one hundred subjects, two or more higher-quality trials with some inconsistency, at least two consistent lower-quality trials or multiple consist observational studies with no significant methodological flaws showing at least moderate effects.

Do you see that?

A. Yes.

Q. And then the last is low quality. Evidence is insufficient to assess effects on health outcomes because of limited number or power of studies, large and unexplained inconsistency between higher-quality studies, important flaws in study design or conduct, gaps in the chain of evidence or lack of information on important health outcomes.

Do you see that?

A. Yes.

Q. Now I'd like to go through as briefly, as quickly as I can the Opioid Treatment Guidelines and have you tell The Court for each guideline whether high-, moderate-, or low-quality evidence was deemed by the committee to exist, okay?

A. Okay.

MS. HARTMAN: Objection.

How is he going to do that without an intense review of the evidence?

MR. JANUSH: Because I'm going -- you don't need to review the evidence if you've read the document. There's actually a conclusion at the end of every point addressing what the outcome of the committee was.

BY MR. JANUSH:

Q. So let's look at recommendations, one, patient selection and risk stratification, page 115.

MR. GABEL: I'd just object on foundation for this line of questioning, just standing objection.

MR. JANUSH: Fair enough.

BY MR. JANUSH:

Q. Recommendations, number one, 1.1: Before initiating chronic opioid therapy, clinicians should conduct a history, physical examination, and appropriate testing, including an assessment of risk of substance abuse, misuse or addiction, and, in paren, the committee notes strong recommendation, comma, low-quality evidence.

Do you see that?

A. Yes.

Q. That's the -- am I correct that this is the committee publishing in parentheses what supports this recommendation, is that right?

A. That's correct.

Q. Okay. And in 1.2: Clinicians may consider a trial of COT as an option if CNCP is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits

outweigh or likely to outweigh potential harms. And, again, committee strong recommendation, low quality of evidence, low-quality evidence, is that right?

A. Yes.

Q. And 1.3: A benefit-to-harm evaluation, including a history, physical examination, and appropriate diagnostic testing, should be performed and documented before and on an ongoing basis during chronic opioid therapy, strong recommendation, low-quality evidence.

Do you see that?

A. Yes.

Q. Okay. Now, let's focus for a moment before moving forward on the subject of prescribing opioids to patients generally before having a rule or a mandate or a precept that patients should first try and fail other traditional sources of pain relief --

A. Okay.

Q. -- that are non-opioid.

MS. HARTMAN: Form objection.

BY MR. JANUSH:

Q. Am I correct that what I just stated, this notion that patients should first have to try a non-opioid pain relief therapy and fail it before being put on

an opioid, is something that -- is a concern that you had?

A. Yes.

Q. Okay. And --

A. Although there would be exceptions, but that as a general rule that I would not want to take -- I did not think it was appropriate to take a patient with very little trial, very few trials with other treatments other than opioids and initially put them on opioids early in the course of their treatment.

Q. So when the -- earlier you said that the committee moved away from where it was in the draft somewhat in its final publication.

Did it move to where you wanted the committee to be on this topic of prescribing opioids as a second-line therapy or a later, a future therapy after a patient fails an initial pain --

A. I think --

Q. I'm not done with my question.

After a patient fails an initial treatment plan of non-opioid products?

A. I don't think they moved to where I thought they should be. I think they moved in that direction, but there were qualifying words that, I mean, I feel they could have been stronger about the jumping to

opioids so soon and, also, that the patient needed to have experience with that doctor, the doctor needed to have experience with that patient. It's part of the same thing actually.

And so, no, I think they moved somewhat in that direction, but I don't think they got to where I thought they should be.

Q. And moving to number two, additional recommendations that the committee arrived at concerning informed consent and opioid management plans, here, too, with both of the recommendations, and rather than go through all of the recommendations, I'm just going to look at the evidence that was reviewed was deemed to be low quality of evidence for recommendation 2.1, is that right?

A. Correct.

Q. And the evidence that was reviewed for recommendation 2.2 was deemed by the committee to be low-quality evidence as well, is that right?

A. Correct.

Q. And moving to three, initiation and titration of chronologic opioid therapy, at recommendation 3.1, there, too, the committee deemed that there was low-quality evidence to support the recommendation, is that right?

A. Correct.
Q. And moving to 3.2, opioid selection, initial dosing, and titration should be individualized, and it goes on.

Here, too, the committee found a strong recommendation but low-quality evidence in the literature to support this, is that right?
A. That is correct.
Q. And moving to number four, methadone, at 4.1, this is an area where the committee found a strong recommendation and a moderate -- moderate-quality evidence.

Do you see that?
A. I do.
Q. Okay. And at number five, monitoring, here we have at 5.1 concerning clinicians reassessing patients on chronic opioid therapy periodically and as warranted by changing circumstances, and there's more language that follows. We have a strong recommendation by the committee with, again, a note of low-quality evidence.

Do you see that?
A. Yes, I do.
Q. And in 5.2: In patients on chronic opioid therapy who are at high risk or have engaged in aberrant

drug-related behaviors, here, too, we have strong recommendation, low quality of evidence.

Do you see that?

A. Yes.

Q. And 5.3, the committee notes, again, a weak recommendation for 5.3 and low-quality evidence.

Do you see that?

A. Yes.

Q. And going to recommendations at six concerning high-risk patients, the committee assesses that it evaluated low-quality evidence at 6.1 and low-quality evidence at 6.2.

Do you see that?

A. I do.

Q. And the same exists at recommendation 7.1, 7.2, 7.3, and 7.4, all of which the committee cited low quality of evidence in making its recommendations.

Do you see that?

A. Yes.

Q. And at 8.1, opioid-related adverse effects, the recommendation is that clinicians should anticipate, identify, and treat common opioid-associated adverse effects, strong recommendation with moderate-quality evidence.

Do you see that?

A. Yes.
Q. Okay. And at 9.1, use of psychotherapeutic cointerventions, 9.1, strong recommendation, moderate-quality evidence.
Do you see that?
A. Yes, I do.
Q. And then at 10.1, the recommendation regarding driving and work safety, low-quality evidence is cited, is that right?
A. Yes.
Q. And at 11.1, recommendations concerning identifying a medical home and when to obtain consultation, low-quality evidence.
Do you see that?
A. Yes.
Q. And at 11.2, there is a note from moderate-quality evidence concerning clinician should pursue consultation, including interdisciplinary pain management, when patients with chronic non-cancer pain may benefit from additional skills or resources that they cannot provide, and here there's an increased quality of evidence to moderate quality of evidence.
Do you see that?
A. I do, yes.

Q. And at breakthrough pain, recommendation 12.1: In patients on around-the-clock chronic opioid therapy with breakthrough pain, clinicians may consider as-needed opioids based upon an initial and ongoing analysis of therapeutic benefit versus risk, and here we have a weak recommendation and a low-quality evidence.

Do you see that?

A. Yes, I do.

Q. And then at number thirteen, opioids in pregnancy, 13.1, recommendation, once again, a low quality of evidence is cited.

Do you see that?

A. Yes.

Q. And at fourteen on opioid policies: Clinicians should be aware of current federal and state laws, regulatory guidelines, and policy statements that govern the medical use of chronic opioid therapy for chronic non-cancer patients, and here, too, there's a low quality of evidence cited.

Do you see that?

A. Yes.

Q. And in total, I counted twenty-one recommendations associated with a low quality of evidence, zero recommendations associated with high-quality

evidence, and four recommendations associated with moderate evidence.

I'm not asking for you to commit that all to memory, but does that, does that seem right that there were about four that were elevated to the moderate standard?

A. I do.

Q. Okay.

(Saper Exhibit No. 6 marked and attached.)

BY MR. JANUSH:

Q. I've marked as Saper Exhibit 6 a document that you produced in response to the subpoena served on you in this case, and it is entitled The Influence of Pharma and Device Manufacturers on APS and other PMA'S, A War Within a War, and you're listed as the author.

Before we get into the substance of this document, can you tell me what this document reflects?

A. This was a, I think it was a draft -- it may have been my final draft -- of my lecture or speech in a debate that I had with -- I don't recall whether this was in the APS domain or whether this was a debate with Doctor Haddox, but it was in that period

of time when all of this stuff was playing out, and I was asked to represent my side of the concerns. This was dated 10-12-11, so within a year of some of this happening, and I gave a presentation, and this was my presentation.

I had a debate, it was listed as a debate with Doctor Haddox at Mass General, requested by members of the pain group at Harvard, and then I had a debate with -- I can't remember with whom -- at an APS meeting. So somewhere in that domain, this was the body of my presentation.

Q. Okay. So since this is 2011, we'll put it aside for the moment and take in time chronologically the document you produced dated March 24, 2010, titled More on the Pain Debate. We'll mark that as Exhibit 7, and then we'll come back to Exhibit 6 in a moment.

(Saper Exhibit No. 7 marked and attached.)

BY MR. JANUSH:

Q. Do you recognize this document?

A. Yeah. Now, this is a different debate.

Q. Okay.

A. So this was a debate chaired by Doctor Schacktiman, and I think this was at AAPM, so the other one must

have been either sponsored -- well, it was at Harvard. It was Mass General. So it was probably the team at Harvard that put that debate together.

So this is a different debate because these are ten minutes, and this talk is much longer than ten minutes.

Q. Okay. Let's get into this debate titled More on the Pain Debate, March 24, 2010.

Where was this again?

A. I don't remember, but it was at one of the AAPM gatherings. It probably was an annual meeting.

Q. Okay. And the title of the debate is The Influence of Industry in APS.

Is that the title of the debate, or is that the title of your presentation within the debate?

A. I don't remember. I don't remember.

Q. Okay. Why don't you take a moment to look through this document and then help explain what your position was within this debate if you can tell from this document.

A. Okay.

Q. Does a review of this document refresh your recollection as to what this debate concerned?

A. Well, yeah. I think that it was, it was -- I regret

that I don't have any more details on this, but I think that I was putting down thoughts to myself, thoughts that had been expressed by Doctor Schacktiman and related to the topics, not the guidelines specifically but just the events that were taking place within the different pain organizations with respect to medical education, funding, choice of programming, various other things that I address here, and so I was putting ideas down for myself for what I eventually was going to talk about in one forum or another.

Q. Can you elaborate on the words that you wrote as follows, quote: Doctor Schacktiman gave an example of how programming was biased and influenced by fear that industry would impose repercussions and consequences for negative programming for their product. A program on opioids has been dinged, not too dissimilar from all the positive programs at AAPM which I protested or the heavily weighted committee for guidelines. Evidence-based is not always the Holy Grail. Common sense and logic must influence policy. Patients die of opioids; drug problems exist, quote.

Can you elaborate on what you were conveying in taking down these notes in preparation

for your debate?

A. Yes. I don't think I expressed a couple of those points very well, so I will explain.

Doctor Schacktiman had been giving some examples of what he considered to be as I said biased programming that were influenced by the fear that there would be financial consequences if there was a lot of negative programming on the opioid or the products.

I had been -- I was criticizing programming at I think it was the American -- at AAPM because there was a strong advocacy list of programs, and none this one year that I was involved in it, none that helped young doctors see a different side of the opioid administration or be taught how to take people off the opioids once they started.

And so that was part of the dialogue, and I was just throwing some thoughts out as I was thinking about my presentations. So that's essentially what I said dissimilar from all the positive programs. By positive I meant advocacy for opioids, and so I didn't say that very clearly, but that's what was going on.

Q. And the fear that industry would impose

repercussions and consequences for negative programming for their product, what was that concerning? Was that concerning negative repercussions in the sense of reduced funding for your organization?

A. Yeah.

MS. HARTMAN: Objection.

THE WITNESS: I was interpreting his remarks, I shared those views, but that's what I was trying to say that there would be somehow or other if they were investigating, they certainly didn't want their product to be disadvantaged. That was the fear and that there would be perhaps some withholding in funding.

BY MR. JANUSH:

Q. In the next paragraph you address within your notes for this debate: Among the solutions, colon, all committees must be balanced in education, et cetera. There must be firewalls that are mutually respected and the identification of safe harbors where the value of industry can be felt in the development of programs and projects.

What did you mean by this?

A. Well, by balancing committees that such as the Opioid Committee that there would have been a

reasonable balance by people who shared my views and concerns about opioids and guidelines and those that had a more liberal or advocacy role, that the committees would be balanced.

The same thing Education Committee where programs are chosen for presentation at the major pain meetings at the major pain meetings, so the programs weren't all in one direction and not in the other.

And then the firewall is, again, that we create a mutually respected attitude so that they did not interfere, industry would not interfere in our ability to come up with appropriate guidelines or programs, educational topics, things of that sort.

Q. And you concluded your notes with the following paragraph. The problem has existed for years.

Let me pause there for a moment. The problem that has existed for years is referring to what, what problem?

A. This, this influence of education and funding and programming and projects and committees, everything we've been talking about.

Q. And when you say this influence, you're talking about the corporate influence by opioid product

manufacturers?

MS. HARTMAN: Objection.

THE WITNESS: Not just opioid. I think it's across the board between Pharma and medical education because medical education is essentially funded by Pharma.

BY MR. JANUSH:

Q. So to ask the question differently, when you say the problem has existed for years, who or what is at the source of the problem?

A. The source of the problem is how do medical societies fund their programs, how do they, how do they keep their members at reasonable dues levels but put on broad educational programs, and that's the same for all the societies, all the medical societies, and traditionally the, you know, the drug companies have been generous in supporting programs.

And I want to make sure I emphasize that a lot of the doctors would not, would not influence the content of their presentations, nor their decisions at committee meetings based upon any funding. But when the influence of money as in politics is there, there are opportunities for problems, and I was addressing that issue.

Q. Thank you for that clarification.

So now to read the complete paragraph, it states: The problem has existed for years, but it was the spiraling increase in opioid advocacy that crystallized the glaring recognition of this revolutionary initiative that transformed a reluctant body of conscientious doctors to the national epidemic of overuse that we see. The programming from the major pain organizations, including APS, and the involvement of industry executives on boards, committees, and influencing their friends could not be ignored. Even the presentation at a professional meeting in which Doctor Haddox tried to dissuade the audience from believing the coroner's report as to the cause of death from those linked to OxyContin overdose. And you end with: It would also help to have statistics.

Can you explain what you're speaking to here with respect to the programming from the major pain organizations and the involvement of industry executives that could not be ignored?

A. Yes, and I'm glad you're asking me to explain it because I want to make sure that it isn't overreaching.

In terms of industry executives on

committees, the only example that I am aware of was with Doctor Haddox. Doctor Haddox is a friend of mine. He was a friend. I still consider him a friend, although we strongly disagree as you can hear.

And I objected to the fact that he -- after he became an industry executive, he remained influential in the American Academy of Pain Medicine, a society which he at one point was president of, of which he was president of and had friends and knew how decisions were made and so forth. He was also helpful in funding the society obviously as an executive of a major-involved pharmaceutical house.

Q. Which pharmaceutical house is that?

A. Purdue Pharma.

Q. Okay.

A. And I was -- and I shared this with him -- troubled by the fact that he was -- the last sentence speaking to the fact that he was asked to give or given an opportunity to give a lecture at one of the meetings, big meetings, from the podium that challenged the autopsies of the OxyContin causes of death as determined by the medical examiners.

So the autopsies concluded death due to

OxyContin, and Doctor Haddox was going down the list of patients in which he refuted the validity of that diagnosis by the medical examiners, and I was troubled by that because I didn't find his argument compelling and I didn't think it was appropriate at that meeting, and I told him so. I told the people at AAPM the same thing.

Q. And when Doctor Haddox was refuting the causes of death on death certificates as having been listed as OxyContin related, he was doing so in what capacity? In other words, who was he employed by?

MS. HARTMAN: Objection.

MS. VICARI: Objection, form.

THE WITNESS: He was, he was at the time an executive of Purdue Pharma, and he was obviously asked or he asked -- I don't know -- but he was given a lecture slot to do so.

BY MR. JANUSH:

Q. Given that Doctor Haddox is your friend and you expressed that you let him know your feelings, how did he react to your expression of being unsettled by his conduct?

MS. HARTMAN: Objection.

THE WITNESS: He disagreed with me. He felt it was important for him to be able to express

himself. We had several conversations over time in which I expressed my views which you've heard and he expressed his views which he disagreed with my views, but throughout that time we remained friendly and we interacted.

BY MR. JANUSH:

Q. Okay. I'm going to --

A. And it's not, you know, you know this I think. I hope you know that I'm not entirely comfortable with the conversation about a friend of mine who I know that I'm, you know, raising certain concerns, but you've subpoenaed me to this deposition and I'm sworn to be honest, and so I'm being honest.

Q. Thank you for that.

I'm going to turn back to I believe I marked it as Exhibit 6, and it's the longer debate notes I believe that are dated 9-27-10 and then 10-12. Sorry. There we are on the screen, and then 10-12-11.

Is it that these notes were written in between this time period, or were there two versions?

A. No. I probably just edited it.

Q. Got it.

A. And those were the two different revisions.

Q. Okay. So Exhibit 6 is titled The Influence of Pharma and Device Manufacturers on APS and Other PMA'S, A War Within a War.

First of all, what are PMAs?

A. Professional medical associations.

Q. So PMAs would include American Pain Society and American Academy of Pain Medicine in your nomenclature?

A. Yes.

Q. Is that right?

A. Right.

Q. What was this document written for, if you can recall?

A. Well, I had these several debates or presentations that I was asked to give my opinion on these matters, and I constructed a document that contained many of my thoughts.

I think this was not a final document from the way I think some of the extra pages reflect, but I don't recall specifically. My typist at the time has retired and is not reachable, so I can't go back. But I was sharing my thoughts and perspectives that reflected more of what I've already testified to.

Q. Okay. I'd like to go through this document with

you.

Is that okay?

A. Sure.

Q. All right. All right. Okay. Let's see. Let's start with page one. Second paragraph, you address that you practice neurological pain care principally in headache for forty years in both academic and private institutions, and you next state: I have served on the boards of APS and AAPM, and I'm a past president of the Headache Society. I have been its ethics chair for nearly a decade.

Let me pause there. What do you do in a role as being an ethics chair for the Headache Society?

A. Well, we would try to establish ethical guidelines that would involve physician behavior related to those members who we had, and if there were behaviors that were brought up that were troubling that the committee would judge those behaviors and try to develop a report to the board.

Q. The next note states that this presentation reflects elements and arguments that I first presented during a program of APS in Baltimore in 2009. Doctor David Haddox, a prominent former practicing physician, a past president of AAPM, and now vice president of

Purdue Pharma and I just faced off.

This looks like --

A. I might have meant -- if I can interrupt you. I'm sorry. I might have meant Boston and not Baltimore.

Q. Okay.

A. That would seem more appropriate because that might have been the Harvard --

Q. Okay.

A. -- talk that I was referring to.

Q. So even if these notes were in draft form for an expected presentation, is it fair to say that these notes reflect elements and arguments that you had already presented in 2009?

A. Yes.

Q. Okay. And at page two, you're addressing that these organizations, and by these organizations, I believe you're referring to the PMAs?

A. Yes.

Q. Both heavily supported by commercial sources, particularly the opioid industry, had acted unethically by failing their expected role to provide balanced and evidence-based educational programming.

Can you elaborate on that?

A. Well, it's another statement similar to what I said

in that balanced programming is that you don't just present one side of an academic argument, clinical or otherwise, and I did not feel that those organizations were presenting balanced educational programming with respect to opioid matters.

Q. And next you get into funding at the bottom of page two and address that. CMEs, continuing medical education, which are generally sponsored by the PMAs are a two billion dollar a year undertaking. Approximately one half of the cost of these major educational programs comes from physician participants and their organizations. Industry spends more than one billion annually to cover these costs, and I see a parenthetical to reference.

When you wrote this, did you, did you look to resource information or reference information to come up with your dollar estimates here?

A. Well, I had to, but I don't remember. I mean, I could not have come up with those numbers without some framework, and so somewhere along the line, I saw those numbers and felt they were reliable, and I simply was noting to myself that I wanted to put down that reference at some later date.

Q. Okay. And so somewhere might there exist a final

draft version that may have that?

A. I haven't found it.

Q. Okay.

A. I will look. I will continue to look.

Q. And at the bottom of page three, I'm going to jump down as it stays with the same theme I believe, you wrote: But in my personal experience -- let me get it into the Elmo.

Actually, I'm going to go above to the paragraph above to make a point here. You were writing about on page three generally continuing your discussion about -- let's see, I'll highlight it -- meetings are subsidized, booths are purchased, physician attendance is underwritten along with meals, honoraria, and social activities. Mailing lists are purchased, satellite symposia developed, and funds for the development of practice guidelines and other doctrines that influence physician professional behavior are granted. Friendships and relationships between physicians, administrators, and corporate representatives are widespread.

Did I read that right?

A. Correct.

Q. And then you say, you go on to say: In my view, none of this is evil or necessarily unethical. Were

it carried out appropriately, these relationships can be beneficial to all parties, particularly patients, right?

A. Right.

Q. Does the next paragraph confirm for you that perhaps it was not carried out appropriately?

MS. HARTMAN: Objection.

BY MR. JANUSH:

Q. I'd like you to read your next paragraph and give me that answer.

MS. HARTMAN: Objection.

THE WITNESS: But in my personal experience, the educational programs of AAPM and APS, particularly as they involve opioid advocacy, were greatly influenced by commercial largess. In my opinion commercial dynamics indeed influenced, if not steered, the selection of abstracts, course topics, and faculty to commercially friendly participants as it involved opioid advocacy, largely ignoring those imposing or exhorting caution against the growing advocacy for opioids for chronic nonmalignant pain.

BY MR. JANUSH:

Q. So having read what you wrote in that paragraph, were you taking the position that this was not

carried out appropriately as per the above paragraph?

A. That was my opinion.

MR. GABEL: Objection, form. I'm sorry. I didn't get a chance to get that in.

BY MR. JANUSH:

Q. Okay. Just to be clear, the preceding paragraph addressed: In my view, none of this is evil or necessarily unethical. Were it carried out appropriately, these relationships can be beneficial to all parties, particularly patients.

And then I asked you to read the ensuing paragraph, right?

A. Right.

Q. And your conclusion as to whether educational programs of AAPM and APS as they involve opioid advocacy was carried out appropriately or inappropriately, and your answer is?

A. I felt it was inappropriate.

MS. HARTMAN: Objection, form.

BY MR. JANUSH:

Q. Thank you.

Now I'd like to address at page five the middle paragraph. Can you read that middle paragraph for the record?

A. APS and AAPM are fine organizations, directed and managed historically by good people with honorable goals. These organizations and their boards, I have sat on both, have made enormous contributions to the welfare of patients in pain, pain research, and to better treatment of pain worldwide. In my opinion, however, the organizations have failed to live up to obvious ethical expectations. And the best example involves the nexus between APS and AAPM, their foundations, and what I call narcopharma, the pharmaceutical manufacturers that produce opioids.

Q. Okay. So as someone who has experience as an ethical director of a -- is it the neurology --

A. The Headache Society.

Q. The Headache Society. Can you explain how, how APS and AAPM failed in your estimation to live up to obvious ethical expectations?

A. Well, I think I've already spoken to those. I'll review them. I think that in the development of guidelines and the balance of programming choices that were made and related educational and activities that there was I felt too close a relationship in some instances.

I don't, I don't know about all the other opioid manufacturers and what their influence was or

how close they were to the decision-makers. I only know selectively and I've testified to that, and I felt that that was just too close and that the programming influenced, it was influenced and biased in a direction that I think was inappropriate.

Q. So just now for clarification, you said I don't know as to all of the manufacturers, but when you said you testified selectively, were you referring to Doctor Haddox and Purdue Pharma?

A. Yes, I was.

MS. HARTMAN: Objection.

THE WITNESS: I'm sorry. Yes, I was.

That's the one example that I had personal involvement in meaning knew about it.

BY MR. JANUSH:

Q. Okay.

A. So, yes, that's what I meant.

Q. And if hypothetically you were presented with a sheet showing the Excel spreadsheet of all of the donations made around the time that this committee made before, during, and after the committee you once served on was formed for the APS and AAPM and it showed all of the various manufacturers that made opioid products, how would that, if at all, impact your determination as to whether the -- whether it

reached beyond Purdue, this ethical issue --

MS. HARTMAN: Objection, form.

BY MR. JANUSH:

Q. -- that you have testified to?

MR. GABEL: Objection, form.

THE WITNESS: It's not the amount of money, but as the amount of these grants grow, there is a far greater burden placed on the organization to have these firewalls, to have -- to go out of their way to establish balance in their choice of programming so that they're not advocating in one direction more than others.

And my feeling was at the time that they were and that there was a greater burden that wasn't being fulfilled, and it had potentially dire consequences because of the type of product we were dealing with, meaning the opioids.

I would have felt uncomfortable but far less concerned were we advocating for an NSAID or a beta blocker just to give you two examples. It wouldn't have been appropriate behavior, but it wouldn't have been as dire in my view.

BY MR. JANUSH:

Q. How, if at all, does the next paragraph addressing the: Twenty years ago opioids were shamelessly

underprescribed for acute, malignant, and end-of-life pain, and today the overadministration of these agents for what many, including me, believe to be inappropriate cases of reported pain has produced a drug crisis in the U.S., and your paragraph goes on.

How, if at all, does this paragraph relate to your prior testimony?

MR. GABEL: Objection, form.

BY MR. JANUSH:

Q. Stated differently, let me strike that and ask this differently. In this paragraph at the end of page five and going into page six, you address that there was an overadministration of opioid products, is that right?

A. Yes.

Q. And you address that this overadministration in inappropriate cases of reported pain has produced a drug crisis in the U.S., is that right?

A. Yes.

Q. And you address that this is an epidemic that in the view of many was bad enough that the government has predictably stepped in to regulate the practice of medicine as it relates to the prescribing of opioids.

Do you see that?

A. Yes.

Q. How did the government predictably step in to regulate the practice of medicine as it relates to the prescribing of opioids?

A. Well, the DEA and the FDA have established various remedial -- attempts at remedial action. The state boards of medicine in various states have developed guidelines for doctors to give opioids which at some point at times are reasonable, at times are unreasonable.

And I'm old enough to remember the Valium parallel. In the late '70s, Valium was overprescribed to anyone who the doctor felt needed a tranquilizer, and there were books written and people went on TV to talk about what Valium had done, and it then became almost criminal to write prescriptions, for doctors to write prescriptions for Valium, and eventually there was regulation and control. We see it today with the benzodiazepines.

The medical profession should not want government to step in and tie our hands and good judgment when we make reasonable judgments about the care of patients which is complex, but if the medical professionals don't control themselves or

medical organizations don't act to control the very things we're talking about, then government is forced eventually to protect society, and they step in, and that in my view is ultimately a bad thing for good medical care.

Q. But in this case, government didn't -- did government step in and limit the ability to prescribe opioid products in any meaningful way?

MS. HARTMAN: Objection, form.

THE WITNESS: Well, there are regulations now that require -- these are mandated by government that may or may not be appropriate in all settings in which opioids may be used.

There's also in my view an overconcern for some of the other drugs that can be somewhat sedating, though not dependency producing such as opioids, that were giving -- the government warns doctors this patient -- government or various agencies warn doctors don't use those drugs together, this is -- you're on a list, you're going to be -- your prescribing patterns are going to be monitored.

That may be a bit of an overstatement, but that stuff is all happening right now, and I think I know a lot of doctors that are afraid to

prescribe opioids at this point because of the overreach and the fear that is being established that has come from all of this happening, and I don't think government had a choice, but that's the predictable, as I said, the predictable involvement of government when doctors themselves don't police the ongoing issues and crises that we encounter with certain medicines.

I myself prescribed opioids for headache patients for a very short time preventively. Eventually I wrote a paper that showed that very few people actually benefited from that, and I pulled way back and don't do that anymore. But there are people being harmed right now because they've been on opiates for a very long time, opioids for a very long time, and the doctors are afraid to prescribe it and for the very reasons that we're talking.

BY MR. JANUSH:

Q. Because of the magnitude of the crisis?

A. One, the fear that they will harm somebody and/or the fear that they will violate principles of care that are being established now, that they will violate government limits, monitoring.

Doctors should voluntarily set elements within our guidelines and the things we've talked

about and not have to have government step in and tell us how to practice. That's not a good thing.

Q. And then moving, I'd like to move on to the next paragraph that addresses: Opioids are indispensable for acute, malignant, and end-of-life pain.

Do you see that?

A. Yes.

Q. Okay. And you address: Gaining regulatory acceptance was an essential and honorable undertaking, but widespread administration for chronic non-cancer pain is another matter.

What are you referring to there?

A. Well, there is a place for opioids in the treatment of pain for patients. Certainly not everybody with acute pain needs to be placed on opiates but some do, and postoperatively, for example, there may be a need for opioids. But not every painful event should require opioids.

But when you get into chronic non-cancer pain, you're talking about leg pain, back pain, shoulder pain, headache, neck pain, arm pain, finger pain, et cetera. That's a different matter.

Now, some are very severe, life limiting, disabling, and so forth, and there may be a need in some of those cases for chronic opioid therapy, but

it has to be, has to be very carefully administered, and it needs to be administered by people who understand the risks and can monitor for the risks.

Q. And does your -- do your next two sentences address the rationale for why you've taken that position that you just expressed because opioids are different than other drugs and for the reasons you wrote at the bottom of page six?

MS. HARTMAN: Objection, form.

THE WITNESS: Let me just --

BY MR. JANUSH:

Q. Please feel free to read it out loud into the record starting with --

A. And despite?

Q. Yeah.

A. And despite arguments to the contrary, opioids are indeed different than other drugs. They produce dependency, craving, euphoria, major endocrine disturbances and tranquilization, and are more likely to be fatal and harmful than most other day-to-day treatments.

Q. So my question was is that why you take the position that widespread administration for chronic non-cancer pain is another matter?

A. Yeah, yes, it is.

Q. Okay. I'd like to move to page seven.
A. I should not write such long speeches.
Q. I'd like to move to page seven where you address -- why don't you read it in your own words, the second paragraph.
A. It was a masterful achievement and in the public good that efforts by members of APS achieved a lessening of regulatory burdens in the use of opioids for the treatment of acute, cancer, and end-of-life pain. But in their zeal and with the financial backing from narcopharma, the initiative evolved from its initial goals to incite an avalanche of opioid prescriptions and widespread availability. Opioids were advocated and became available not just to patients reporting convincing, severe pain, but to almost anyone who reported pain, whether that pain was convincingly severe or in some cases believable at all, whether other remedies were a better choice, whether the patient was trustworthy and compliant, whether the physician knew the patient at all.
Q. Do you believe these words today?
A. Yes.
Q. And then you -- why don't you continue with the next paragraph.

A. It is reasonable to ask the question: Was this an accidental outcome derived from a well-intended effort by well-meaning professionals, or did this epidemic begin as a result of a creative and brilliant, though stealth marketing strategy, energized through financial incentives to cash-starved organizations with the help of willing professionals? I think both.

Q. Do you believe those words today just as when you wrote this?

A. Yes.

Q. Let's move on to the final paragraph on this page.

A. In my opinion APS, AAPM, and its leaders along with narcopharma coalesced for three reasons in the initiation of the opioid strategy: Because it was necessary to improve our treatment of acute pain, to financially support PMAs and perhaps physician advocates, and in the case of Pharma, to increase market share and profit through corporate duty, their profit, dash, their corporate duty.

Q. And do you believe all of these words just as you wrote them in 2011?

A. Yes, I believe different dynamics. I'm not sure all, all of the businesses, all of the opioid companies, producing companies, were of equal

involvement in various of these activities. I just don't know enough about one from another except the limited experience that I do have, and I've shared that.

Q. Would it be a correct statement that as a general matter in the case of Pharma as you wrote, you believe that, that APS, AAPM, its leaders, along with the pharmaceutical manufacturers worked together to financially support the PMAs and physician advocates to increase market share?

MS. HARTMAN: Objection form.

THE WITNESS: You know, I think that's probably true, but I can't say that with absolute certainty. I think it's logical.

BY MR. JANUSH:

Q. Okay. And you address at the top of page nine that the APS and its foundation led an early brigade. Professors June Dahl and David Jorensen of the University of Wisconsin were funded to undertake an initiative to visit boards of medicine in state after state to argue the importance of lessening the regulation of doctors who prescribe opioids for cancer, acute, and end-of-life pain. They succeeded. Their initiative was funded from perhaps several sources, but certainly APS, which in turn

was heavily supported by narcopharma. The advocates' university has received grants on their behalf from narcopharma. Their success is a matter of record.

Do you see that?

A. Yes.

Q. And you were speaking -- are these the folks you were speaking about before that traveled the country around to visit boards of medicine in different states?

A. I believe that was the program, yes.

Q. Okay. And when you wrote this, did you have specific information that their initiative was funded from APS?

A. I can't remember exactly. I think I did. I certainly wouldn't have just assumed that.

Q. Okay.

A. But I think that there -- I mean, I've had discussions way back with David and with June Dahl, and I think that we knew that that was a funded initiative. I can't say with certainty.

There was another funding agency called the Mayday Foundation in those days. I don't know if it's still available, if it's still in existence, but I know they funded programs on advocacy for

opioid usage.

Q. And you also address: The advocates' university has received grants on their behalf from narcopharma.

And you're referring to the University of Wisconsin, is that right?

A. You know, I would not have made -- I'm a graduate of the University of Wisconsin. I would not have made that statement had I not known something factual, but, or heard something that I believed to be factual, but I cannot recall where I would have got that information from.

Q. Okay. And you next move into the Joint Commission initiative which you wrote was also supported by APS and employed an important new concept, the fifth vital sign, a welcomed and well-intended initiative conceived by Doctor James Campbell, a highly regarded and influential neurosurgeon from a prestigious medical center, then president of APS and later chair of its foundation.

Do you see that?

A. Yes.

Q. When you wrote this, did you, did you know that the Joint Commission initiative concerning the fifth vital sign was indeed supported by APS?

MS. HARTMAN: Objection, form.

THE WITNESS: Well, I must have if I said that. I mean, as I say, I didn't just make that stuff up. It's a long time ago as you know, and I don't recall all of the sources of my information at this point.

BY MR. JANUSH:

Q. Would the fact that I skipped or didn't read the fact that Doctor James Campbell was noted to -- by you to be a friend in the ensuing sentence that I didn't read.

Do you recall having discussions with Doctor James Campbell about the Joint Commission initiative regarding the fifth vital sign and support by the APS?

A. I remember a board meeting that I was at where Doctor Campbell talked about the concept of a fifth vital sign initiative to put pain on the map so to speak -- that's my phrase -- and that to make the treatment of pain in a hospital setting more efficient because there was, in fact, a widespread concern -- and I think it was valid -- that pain was not well attended to in the hospital by people postoperatively and in other ways.

And so this was an attempt, an honest attempt in order to put criteria for hospitals

through the Joint Commission in order to better attend to the pain of the patients, to ask them just like we would do blood pressure and pulse readings.

So it was the fifth vital sign, respiration, blood pressure, pulse, and -- what did I forget? And, of course, pain. Respiration, pulse. I'm forgetting one of them. How do I do that? At any rate, that was the basis of it.

Q. Okay. And you started --

A. Temperature. That was the other fifth.

Q. You said that this began as an honest effort, and I'm going to turn your attention to reading the top of page ten, of the paragraph at the top of page ten, and after you're done I'm going to ask you a question.

A. Do you want me to read?

Q. Sure.

A. Where, where do you want me to start?

Q. It was directed at acute pain.

A. It was directed at acute pain, which was laudable. It has morphed into something else. The guidelines, well meaning as they might have been, suffer greatly from lack of perspective and wisdom, the most glaring of which is failure to distinguish acute pain from chronic pain by treaters who would

otherwise not have a clear sense of this distinction, and by the absence of when enough is enough. This program revolutionized hospital care through accreditation criteria. Development of these guidelines within the Joint Commission was with the assistance of key aggressive opioid advocates.

Q. What are you referring to when you write the development of these guidelines within the Joint Commission with the assistance of key aggressive opioid advocates?

A. Well, I don't remember all the details at this point, but it's my vague sense and recollection that there were discussions amongst all of us, how did the Joint Commission, and people would say, well, they visited the joint college, they visited the Joint Commission and made this pitch to them and convinced them to write guidelines or to establish guidelines on the use of pain control measures within hospitalized patients.

Q. I'm going to take you to page -- I'm going to skip forward in the interest of time and since we've covered some other material that's similar earlier to paragraph fourteen on page fourteen -- excuse me -- where you're addressing the most odious

example of what you believe to be biased influence over practice.

Can you read that paragraph and talk to us about what this means?

A. I must also say if I can --

Q. Sure.

A. -- take the liberty that these comments were to be given to my colleagues in the various debates. These were not for public distribution if you know what I'm trying to say here, and some things would have been said differently had I been putting these comments together for more public debate, more public distribution.

Perhaps the most odious example of what I believe to be biased influence over practice was reflected in personal experience while on the APS/AAPM committee to develop opioid guidelines. It was a project funded through the organizations, who received grants and commercial support from narcopharma. Almost every member of the twelve to fifteen member committee, except for perhaps two of us, was a well-known aggressive advocate of unrestricted opioid therapy for chronic nonmalignant pain. At the very least it was not a balanced group of advocates and cautionaries. The committee's

organizational leaders and research assistants were honorable and scholarly in their approach, but the decision-making and ultimate guidelines were the result of committee member decisions. At a critical point in the process, I recommended that the guidelines required a minimal standard for competency for prescribing physicians. I also recommended that pretreatment criteria be established so that opioid initiation would require more than simply the complaint of pain. The committee would have nothing of either competence training -- it should have been nor pretreatment criteria. My recommendations were soundly rejected. I appealed but failed. There would be no barriers to prescribing or standards, even self-assessment of competence. In the committee's view, any licensed physician of any skill and learning with any level of experience in the treatment of pain or knowledge of opioid pharmacokinetics who had a DEA number could prescribe opioid to any patient without limiting criteria, restrictions, or background considerations.

Q. Let me pause you there. So far what you've read, do you agree with that language as you sit here today?

A. Yeah. It's a bit harsh, but I don't disagree with

the sentiment behind it.

Q. Okay. And earlier when you said, you know, you were writing for your peers and not for public consumption, was that intended to mean that you were writing in a way that's most honest before your core group of people that you work with in the same field?

A. That's what I meant.

Q. Okay.

A. Is there a question on the table?

Q. Yeah. Well, first I asked you if these words mean, you know, the same today as they did when you wrote them.

A. Right.

Q. And now I want to have you read at the top of page sixteen where you were headed before I interjected with that question. Go ahead.

A. I would not allow my name to be associated with the documents, and I publicly resigned. In the end after I had departed, some small steps were taken in the direction of my recommendations, but by the time it was well -- but by that time it was well beyond the point at which I could comfortably participate. I do not know with certainty, but I cannot avoid believing that undisclosed commercial conflicts of

interest were influential. My recommendations were modest and relevant, and resistance to them was intense and absolute.

Q. Do you stand by these words today?

A. Yes.

Q. And in the ensuing paragraph, you write about a committee member who spoke with you following your departure.

Can you read that?

A. Following my departure, one other committee member who chose not to resign said to me they're mad. By that she meant that they are out of their minds.

Q. Are you willing to disclose who that committee member was?

A. I don't know if that's fair to that person without perhaps me talking to her first.

Q. Now I want to get into what you viewed to be the consequence, consequences to this decade-long undertaking.

First, what is the decade-long undertaking what you're addressing?

A. The aggressive opioid advocacy --

Q. Okay.

A. -- and liberalization.

Q. And what are the consequences that you are

addressing?

A. Well, again, these are data that I found somewhere in the literature online. Failed poisonings quadrupled in seven years. The number of deaths involving methadone increased sevenfold between '99 and 2006. The retail distribution of oxycodone increased by six hundred and sixty percent between '97 and 2003. Ninety percent of all drug deaths are now due to opioids with the majority due to hydrocodone, methadone, and OxyContin. One life is lost every fourteen minutes due to prescription drugs, largely opioids.

Q. And, again, in order for you to write this, did you do research to find factual underpinnings?

A. I had to. There would be no way to come up with those numbers.

Q. And rather than take you through the entire document, I'm going to end with this. At the bottom of page eighteen, can you read from in our eagerness?

A. In our eagerness to address a glaring and troubling problem of undertreated acute cancer and end-of-life pain, a colossal public health crisis has evolved. APS and AAPM and its members have participated, if not promoted, this crisis by failing to assure the

presentation of unbiased, balanced educational programs and guideline development, thereby protecting the public from the commercial influence through undisclosed support from the opioid industry. In failing to do so, the organizations failed to protect patients. The government has now stepped in to solve a problem that should have been solved by professionals and their organizations.

Q. And do you believe these words as you wrote them back in 2011?

A. I do.

Q. How would you describe the nature of the opioid crisis as you've termed it in the present, at the present time?

A. Well, there's a bit of a boomerang effect or maybe a pendulum effect and you hit the wall, and now doctors are fearful to use opioids, and there are harms coming from -- in some ways from people who need and have to be maintained on opioids at this point anyway, and there are many doctors that are fearful because of government issues and regulatory and state issues, licensing issues, and perhaps malpractice issues.

On the other hand, I think that it is better that we're now restricting our use of opioids

as compared to the way it was in the past. Unfortunately, this is the same pattern as we saw with other drugs that were misused or overprescribed, and then there's the they hit the wall and overreaction in the other direction sometimes.

Q. As you sit here today so many years after voicing your concerns, do you feel vindicated?

A. I don't feel good about anything here including talking about this that involves my friends who I respect. I don't know if they would call me their friends any longer, but I think that this is -- this whole dilemma should have been, should have been prevented I think by reasonable efforts, and if we saw there was harm happening, we should have taken steps ourselves to police what we were doing and stopped it, and those of us that are teachers should have been teaching a different perspective, a moderate perspective.

And so I don't feel good about anything. I don't feel vindicated actually. I feel troubled by the fact that I'm torn between loyalty to my profession and my friends and doing what I think is in the public good by revealing what I know. But I don't feel good about it at all.

Q. I don't have any further questions at this time.
Thank you, Doctor, for your testimony today.
A. You're welcome.
MS. HARTMAN: Defendants will have questions, but we're going to maybe take a five-minute restroom break.
THE WITNESS: Sure.
THE VIDEOGRAPHER: Going off the record at 4:44 p.m.
(Off the record at 4:44 p.m.)
(Back on the record at 4:56 p.m.)
THE VIDEOGRAPHER: We're back on the record at 4:56 p.m.
EXAMINATION BY MS. HARTMAN:
Q. Greetings, Doctor Saper. My name is Ruth Hartman, and I'm here on behalf of Endo Pharmaceuticals and the manufacturing defendants.
Based on your testimony so far, would it be fair to say that you advocate the use of opioids for the treatment of acute pain?
A. When it's, when it's appropriate, yes.
Q. Okay. And is it fair to say that you also believe general practitioners can prescribe opioids for acute pain?
A. If they're acknowledgeable about the opioids and how

to prescribe them, I think that that's a necessary responsibility for primary care physicians.

Q. Could you give me some examples of situations where general practitioners may prescribe opioids for acute pain?

A. Well, treatment of a fracture, treatment of perhaps acute injury of some sort, broken bone, a severe sprain, not necessarily as a first-line drug, but certainly along the course of treatment, I would think that a primary care physician.

But I want to say, qualify, again, that I believe that opioids even in the acute form need to be given by people who understand the implications of opioids and how they can affect everything from heart rate and the EKG changes that can occur with some of them. So we have to assume not all doctors -- whether they're primary care or neurologists or whatever -- are equally knowledgeable about everything.

So first they have to be knowledgeable, and then the patient has to be -- it has to be suitable in that patient.

Q. Could we talk a little bit about Exhibit 6 which was your address? It was about eighteen pages long. I just have one question. You said if this were to be

given to a public audience, it might read differently.

What do you mean by that?

A. Sure. I think I was a bit harsh. I don't retract the words or the sentiments, but I think that I was lecturing to my colleagues and with a sentiment that we needed to do better as a profession and we let this get out of hand and speaking to the -- my colleagues in the pain world, pain treatment world.

If I were to say this in a more public forum, I wouldn't be as specifically critical, but I would not hold back on my concerns for what's happened here.

And I was asked by the former questioner as to whether I felt vindicated. You know, a lot of people have died, a lot of families have been altered, and there's no way to feel good about any of this, and I understand the basis of his question. I don't mean any disrespect on that point, but this is, this is just I think a crisis, and if we understand how it happened, we may be able to prevent it from happening again. I think that's how I feel.

Q. Okay. Well, you said you were a little harsh.

I mean, you were trying to convince

people of your position?

MR. JANUSH: Move to strike, move to strike. Objection.

THE WITNESS: Well, it's hard to explain. I mean, you can soften words and express the same sentiments.

BY MS. HARTMAN:

Q. Okay.

A. I don't know how you folks talk to each other as attorneys, and I think if you were talking to a body of attorneys on some of the things that attorneys do or don't do, you know, I think that your choice of words might be different than if you were talking on ABC News or Fox News about the legal profession.

Q. Sure.

A. You might say it a little differently.

Q. Yes.

Do you support the aggressive treatment of pain?

A. Yes.

Q. And what does that mean?

A. Well, first you listen to the patient and you take the patient's symptoms seriously. That doesn't mean that you believe everything that is said. We all, just like you as an attorney, you have to take

things and interpret them.

But pain needs to be treated. Chronic and acute pain need to be treated, but we have enormous ways, an enormous number of ways of treating pain, and so one can be very aggressive without prescribing opioids.

Q. But you could prescribe opioids to treat a chronic pain if you have the requisite knowledge in your view?

MR. JANUSH: Objection.

THE WITNESS: If one has the requisite knowledge, requisite knowledge, and if the patient is an appropriate candidate for chronic use.

BY MS. HARTMAN:

Q. Okay. All right. You talked a lot about CMEs and industry groups, correct?

A. Uh-huh.

Q. And I think, and correct me if I'm wrong.

A. PMAs.

Q. PMAs. But also PMAs offer CMEs, is that correct?

A. Yeah.

Q. Okay. And you say PMAs rely a lot on pharmaceutical companies for their funding, is that correct?

A. Yes.

Q. Are there other alternative sources of funding

besides pharmaceutical companies for the PMAs?

MR. JANUSH: Objection.

THE WITNESS: Well, there are dues, and there are -- not all is from the pharmaceutical company. I mean, there's device manufacturers. There are sometimes government grants for various projects that would be done within that society.

But a large amount of money, like, percentage of money, does come from the pharmaceutical industry.

BY MS. HARTMAN:

Q. And if the pharmaceutical industry stopped funding the PMAs, what would happen to them?

MR. JANUSH: Objection, calls for speculation.

THE WITNESS: Some could not survive.

BY MS. HARTMAN:

Q. But don't the PMAs offer an important source of CMEs?

A. Of course, yes.

Q. Okay. So CMEs would be affected?

A. Yes, they would be.

Q. You've conducted clinical research before, correct?

A. Correct.

Q. Has any of your research been funded by medical

device companies or pharmaceutical companies?

MR. JANUSH: Objection.

THE WITNESS: Yes.

BY MS. HARTMAN:

Q. Could you name a few?

A. Sure. Amgen, Alexzo, Doctor Reddy.

You know what that is?

Q. No.

A. It's an Indian company that does a lot of -- they do a lot of studies in the United States.

Gosh, I think twenty or thirty different, all the major companies I think over the years. My first, my first study was in 1975, and I've been doing them ever since.

Q. Okay. Would you say what percentage of your research is funded by medical device companies or pharmaceutical companies?

A. Probably, because we're not doing basic research, we're essentially doing drug studies and device studies, so probably ninety-five percent.

Q. Okay. But despite this funding, are you still able to be objective in your research?

A. Yes.

Q. Okay. And you're not the only doctor who can conduct research objectively after receiving funds

from a medical device or a pharmaceutical company, correct?

A. That's correct.

Q. Great.

And despite the funding, you're still able to conduct your research with scientific integrity, correct?

A. Well, it's not only conducting research. I mean, the research is essentially guided by FDA-approved formats for those research projects.

If you ask the question differently about interpreting research, interpreting research or prescribing those drugs after they've been approved, yes, I do, and I use ethical standards to do it, and so do most doctors I believe.

Q. So you're not saying here today that accepting funding from a pharmaceutical company means someone is unable to be objective?

A. That is correct.

Q. Okay.

A. I'm not.

Q. And you're not saying that accepting funding means someone is unable to act with scientific integrity, are you?

A. That is correct, I'm not saying that.

Q. Okay. And you've also provided consulting services for medical device and pharmaceutical companies, is that correct?
A. Yes, I have.
Q. Approximately how many companies?
A. Well, over the years, probably thirty, thirty-five over the years, maybe even more.
Q. Okay. And were you able to be objective in your opinions?
A. I believe I was.
Q. And were you compensated for your services?
A. Do you mean, like, lectures you're talking about?
Q. Yeah.
A. Yeah, I would always be compensated in one way or the other. Now, some lectures were not compensated for, but mostly, yes.
Q. So you can be objective even though you're receiving compensation?
A. I believe I can be, and I believe most of my colleagues can be.
Q. Okay. Do you agree that it's important for pharmaceutical companies to consult with top experts in their particular fields?
A. Yes.
Q. Why is that?

A. Well, because pharmaceutical companies need guidance. They often need to hear what we feel are appropriate needs in terms of drug development, clinical, clinical drug's development, and I think and I must say I have a good relationship with most of the companies in terms of the advisory boards that I've sat on over the years. So I think it is an important dialogue back and forth.

Q. Okay. In fact, it would be a problem or it could be detrimental to patients if pharmaceutical companies did not consult with experts in their fields?

A. I believe that to be true.

(Saper Exhibit No. 5 marked and attached.)

BY MS. HARTMAN:

Q. Okay. I want to introduce Exhibit 5. I took this off a website, your website.

Do you recognize this study referenced in the website?

A. Do you mean Allergan?

Q. Yeah.

A. Yes, of course.

Q. So are you running a migraine study sponsored by Allergan?

A. Currently, yes, we are.

Q. Okay. What's involved in that study?
A. Well, it's a drug. It's a -- we have a bunch of studies, and I don't want to misspeak here. I think it's a CGRP antagonist that we're studying. I think it is. I don't keep which drug from which study always or which company, I don't keep it always straight because we have many, but it's a headache drug that we give, and we've done several studies for Allergan over the years.
Q. Okay. But does Allergan have any ability to influence the outcome of your study?
A. The outcome of the studies.
Q. Uh-huh.
A. Well, the studies are approved by the FDA.
Q. Okay.
A. And the data is collected by the drug company such as Allergan.
Q. Right.
A. And they usually will interpret the data, and then those people who they ask to write abstracts, in other words, people like myself or others or write a paper, we will look, we should look at that data, you know, and if we're principally or primarily if we're first authors, and so, yeah, there's a process.

Now, can there be mischief along the line? Yeah, of course. Of course there can be mischief. There has been mischief over the years.

Q. But that's more of an exception than the rule, is that correct?

A. I believe that to be the case, yes.

Q. And you don't conduct your studies that way. There's no mischief when you get funding from the companies?

A. Not that I'm aware of.

Q. Okay. You tend to disclose any funding that you receive in your articles, is that correct?

A. Say that again.

Q. When you write an article, do you disclose any outside funding that you receive?

A. Yes.

Q. Okay. And why do you do that?

A. Well, it's required now.

Q. Okay.

A. Yeah, it's for the last several years. You probably are familiar with what's referred to as the Sunshine Laws, and every dollar directed at a physician, whether it's for research or for a fountain pen that somebody would drop off, ballpoint pen, you know, everything has to be reported.

And so the answer is yes, you are obligated and the journals require it as a condition of publishing the paper and giving a talk. Before you give a talk, you have to. I think that's a good thing.

Q. Okay. Why is that?

A. Because I believe that it's important for the audience to know where that doctor has received funding, and it helps I think promote better interaction between audience and doctor.

I don't participate, for example, in drug-funded, current drug-funded talks and which are essentially marketing talks by doctors. I don't do those.

Q. But you do do studies?

A. I do studies.

Q. Yeah. That's correct.

And do you know for the guidelines, let's go back to Exhibit 4. Do you know whether the authors of the studies disclose any money that they received from outside sources from companies in this document?

A. Isn't there a place where --

Q. Yeah, I'd like to --

A. There is a place back there, and I think that from

the last time I looked at it, I think some of the disclosures had a monetary amount and others did not.

Q. Okay. And you mentioned Jane Ballantyne as someone on the committee, is that correct?

A. I did.

Q. And she supported some of your views, is that correct?

A. Yes, she did.

Q. Okay. I'd like to call your attention to the Exhibit 4 with the Bates number ending 158.

A. Hold on a second. 158?

Q. That's what we were just looking at.

A. Got it.

Q. Yeah. If you look down at her name at the bottom of the page, do you see that?

A. Uh-huh, yes, I do.

Q. She received funding from Endo Pharmaceuticals, correct, or she served on an advisory panel involving --

A. Yes, yes, she says that, yes.

Q. And yet she still shares some of your views, correct?

A. Yes.

Q. So that suggests you can receive funding and be

independent?

A. Yes, you can.

Q. And did the final guidelines adapt any of your recommendations because when I looked through it, it seemed as if it wasn't -- it did sort of include some of your recommendations, like, if you look on page 142.

A. Uh-huh.

Q. That's topic one, patient selection and risk stratification. And then if you look on the next page --

MR. JANUSH: Objection.

Is there a question?

MS. HARTMAN: Yeah, there is.

BY MS. HARTMAN:

Q. It says, the first full paragraph says: A thorough history and physical examination, including an assessment of psychosocial factors and family history, is essential for adequate risk stratification.

That was something you were advocating for, right?

A. Right.

Q. I mean, one thing you said was I don't want a doctor just to prescribe a drug without knowing this

patient's history.

A. Uh-huh. No, I agree. I've acknowledged in my direct testimony that there was a movement in the direction of some of the things, and I'm not sure that I'm the only one that wanted these things in there. I'm not suggesting that.

Q. Right.

A. But, yes, I've acknowledged that they did move in the direction. I don't think they moved as far as they should have gone.

And I think one point I made about we probably, because of the nature of opioids and the risk issues, we probably shouldn't prescribe opioids the first time or maybe even the second time we see a patient except under maybe the most extraordinary conditions because we will not have even had a time -- people come into our offices with boxes of records. Wouldn't it be reasonable to read those records in detail before we prescribe so we know what's gone on before, you know. I'm sure it's parallel to you as an attorney having to read records and the data.

Q. Right. Okay. Well, could I ask you to turn to the next page on topic two?

A. Yes.

Q. And then that's informed consent and opioid management plans.

Do you see that?

A. Yes.

Q. And then the next page, the first full paragraph, it says: It's important for clinicians to discuss a COT management plan before initiating a course of treatment and on an ongoing basis while patients are on therapy. The COT management plan includes goals of therapy, how opioids will be prescribed and taken, expectations for clinical follow-up and monitoring. See section five. Alternatives to COT, expectations regarding the use of concomitant therapies, and potential indications for tapering or discontinuing COT which may include failure to make progress towards therapeutical goals, intolerable adverse effects, or repeated or serious aberrant drug-related behaviors.

So this seems to suggest a plan should be put in place before a patient is prescribed an opioid.

A. Correct.

Q. And you agree with that, don't you?

A. I do agree with that.

Q. So it seems as if you might have had an influence on

the ultimate guidelines that were enacted in 2009, would that be correct?

MR. JANUSH: Objection.

THE WITNESS: I think that there are areas -- and you pointed to a few of them -- where -- and I don't want to take credit for all of this or any of these changes. They may have well been promoted by other people.

But the fact is that as I've acknowledged, what prompted my resignation was that these weren't a part of anything that I saw, some of these things, and I still don't see a credentialing of physicians criteria for knowledge about opioids and a reference to a methodological steppage toward opioids by trying other things first.

And so it's not all there, but certainly they made progress in my view.

BY MS. HARTMAN:

Q. Okay. And isn't it true you said you were professionally busy during the time these guidelines were written?

A. Yeah. I'm trying to remember my lifestyle at that point, but I was busy, and I couldn't attend all the meetings.

Q. Were the meetings via telephone?

A. Some were, some were. Again, I don't remember all of the details. I remember one meeting, maybe two meetings, but I apologized to them as you saw. So I acknowledged that I couldn't attend all the meetings.

Q. Do you think had you attended more meetings, you would have been able to persuade more people of your views?

A. That's possible. I know I knew a lot of people around the table, not all of them, but I knew a lot of people around the table.

My views were pretty clear in my letter to Doctor Chou and then the other people that I -- well, the letter to Doctor Chou is just to Doctor Chou. It wasn't sent around the table. But I think he did send them to other people.

So I think my views were both expressed personally by me and publicly and in my letter to Doctor Chou.

Q. But you've mentioned before that you think Doctor Chou is a serious fellow.

A. I do.

Q. Yeah. And that he took these guidelines seriously?

A. I do.

Q. Do you think anyone else on the committee didn't

take this seriously?

A. I don't know if I would use those words. I think that there were people that might have had preconceived notions on how they were going to respond to any restrictions that might be advocated by some of us. But I'm not able to read their minds.

Q. You talked a little bit about -- well, let's look at the first letter you sent to Doctor Chou. That is Exhibit 2.

A. Okay.

Q. Okay. This letter talks about criteria for initial administration of opioids, is that correct? You want doctors prescribing for chronic pain to have some sort of criteria for initial administration?

A. Yeah. Yes. I'll answer it simply yes.

Q. Yes. Okay. And you want the physicians to have proper training, is that correct?

A. Proper knowledge, proper training, yes.

Q. But that's more specifically geared for chronic pain as opposed to acute pain, is that correct?

MR. JANUSH: Objection.

THE WITNESS: Let me try to explain it in a different way.

BY MS. HARTMAN:

Q. Okay.

A. I don't want to interrupt your train of thinking or your line of questioning.

A doctor has to understand pain disorders. Pain is a specialty and pain care is a board certified specialty, and knowing what could be tried other than opioids and what has failed are two of the things that you need to find out about, and what illnesses that that patient has may contribute to pain.

I mean, it would -- you have a parallel in the law. I mean, if you're a specialist in a certain area, you know a lot more about that problem than you do if you're not a specialist in that area.

The same thing in medicine. I'm not trying to make business for specialists. I'm simply saying we're dealing with serious issues here, and so if you come to me and you say it hurts here and I can't work because I can't concentrate, I can't think clearly, I'd better know how to diagnose that. I'd better know how to prescribe for that in a variety of ways, what tests to order, what's available that might work for you, rather than just reach for an opioid prescription pad. That's what

I'm getting at.

Q. Right. And it sounds as if to some extent the guidelines addressed your concern by trying to develop background of the patient's history and medical condition?

A. Some of that, yes, some of it did.

How about, how about the issue of whether -- I don't know enough about the different categories of law, but, you know, let's say, let's say a person does contracts and is a business contract lawyer, and someone comes to him or her with a complicated IRS issue, you know. Are you going to sit there and prescribe a legal remedy for that person or are you going to say, no, I think you need to go and talk to my colleague who specializes in taxes.

Q. Right. So you think that doctors just need to educate themselves or --

A. If not themselves, to be educated properly and what are the risks here. You know, I'll bet you that if you were in your work here to defend the company, and I respect that, were to ask some practicing attorneys, some practicing physicians what are the cardiac implications of methadone, what do you have to worry about with methadone, I'll bet you a lot of

physicians -- experts in certain areas -- wouldn't know the first way to answer that question because that's not their area.

Q. Right.

A. Wouldn't you want it to be their area if they're going to prescribe that drug?

Q. Sure.

But there are resources that a doctor can use, is that correct, he or she can look into a prescribing book --

A. Could.

Q. -- or some sort of medical --

MR. JANUSH: Objection.

BY MS. HARTMAN:

Q. I'm just asking what could a doctor do in that situation?

A. Well, the doctor can obtain certain pieces of information, but that, did you ever hear the -- is it all right to ask you a question? Let me just say there's a phrase out there to referencing opioids, it takes five minutes to say yes and thirty minutes to say no.

That's part of the dilemma. Doctors are pressured for time, patients are saying I hurt, I hurt, do something, Doctor. If you say, okay, I'm

going to give you some Percocet or oxycodone or something, they're happy. They feel they'll get relief right away, and to find something else, to look things up takes time. Time is a premium. That's reality, and so we want that doctor educated before that patient walks in the room.

Q. Okay. Are you still associated with AAPM?

A. I think I'm still a member. I don't have any leadership or teaching responsibilities. I do think I pay my dues.

Q. Do you still --

A. My office pays my dues.

Q. Do you believe that AAPM is a worthwhile organization?

A. Absolutely.

Q. Okay. Have you ever served on any committees or subcommittees?

A. Oh, yes, over the years, many.

Q. Could you tell me a few?

A. Oh, geez. You know, specifically I can't tell you. I was on the board. I've been on a lot committees --

Q. Okay.

A. -- in a lot of different societies, and I'm not sure without thinking about it.

Q. Do you know what year?
A. What's that?
Q. What years?
A. The years, yeah. The years would have been the late '80s, early up to mid '90s I think when I was most active. Actually, I think I was pretty active up until into the 2010 area. I used to give the headache talk at some of the annual meetings.
Q. Do you still attend their conferences?
A. I haven't for several years now.
Q. Okay.
A. I'm doing less general pain work, and so I don't belong to that organization.
Q. Okay. What about APS?
A. I think it's about the same. I think I still belong to the organization. I still get the Pain journal. So you get it as part of the thing, but I haven't attended.
Q. You're a board certified neurologist, is that correct?
A. Correct.
Q. And you're also a board certified pain medicine specialist, is that correct?
A. Well, yes, I was board certified pain management specialist, but when I stopped seeing a lot of pain

patients, I let that special -- that certification lapse. I didn't want to take the board certification again because I'm not seeing general pain.

I'm board certified in neurology, and I'm board certified in headache which is a separate board.

Q. Okay. And to maintain your medical license, you need to take continuing medical education, is that correct?

A. Correct.

Q. Or the CAMs that we talked about before?

A. CMEs.

Q. CMEs, correct.

So, and there are standards in place to govern the relationship between CME providers and commercial interests?

A. Yes.

Q. Okay. Are you familiar with the Accreditation Council for Continuing Medical Education?

A. Yes.

Q. And they set forth certain standards, don't they, for CMEs --

A. Right.

Q. -- and commercial interests?

A. Yes, they do.
Q. Is that an appropriate way in which the medical profession can be governed to guard against commercial overinfluence?
A. Well, govern how? They basically give -- the ACCME group gives the CME credits, and they generally work through organizations by setting up standards for what you have to do to give a talk, I think also to write a paper, to publish it in their journal, and you have to show the companies that you have conflicts of interest with.

And there's all kinds of guidelines that are now out there. The last couple of years have become increasingly intense in terms of ethical guidelines.

Q. Okay. I have a question. I know plaintiffs' counsel referenced that you spoke today.

Have you met with plaintiffs' counsel before today?
A. No.
Q. Did you speak to plaintiffs' counsel on the phone?
A. I was called -- I was subpoenaed, and I placed a call to -- was it your office that I called? I don't know. We needed to get some of the details in terms of what this meant in terms of timing, and the

initial location was different than this. So.

My secretary did most of that calling. I had one call, not with either -- I didn't speak -- did I speak to you?

MR. MILLICAN: It was with me.

THE WITNESS: Okay. One time, but it wasn't about content. It was about location, whether the room would be big enough, whether we'd have other rooms available. That's all.

BY MS. HARTMAN:

Q. And you spoke to plaintiffs' counsel today, though?

A. I did.

Q. And was that substantive?

A. Not really. I mean, we talked about -- the discussion centered around the kinds of things that he wanted to cover and it was going to be the stuff that I sent him, and that was about the extent of that discussion.

Q. Did you send those documents in response to a document subpoena?

A. Yeah. I mean, the subpoena said please forward all relevant documents, and so we started to search for as many as we could find.

Q. Do you know if you have any other documents in your possession about the 2009 Opioid Treatment

Guidelines in addition to what you already produced?
A. Not about the -- no. As a matter of fact, the opioid guideline document that I have is -- doesn't have all the pages attached to it.
Q. Right.
A. So I don't have anything else that we can find.
Q. Okay. Did you have any notes about those guidelines?
A. I don't think so. I mean, I read, I read the guidelines when they first came out, I think I read them in the journal, and I had a copy which was not the appendix. I had a copy of the first earlier pages, first set of earlier pages.

And I haven't even reviewed them up until I did go over them in anticipation of this deposition.
Q. Okay. How much time did you spend preparing for this deposition?
A. I think about two hours of reading the material, maybe an hour and a half. I don't know. My secretary spent more time trying to find everything than I did.
Q. Do you know if you have any other documents in your possession about the AAPM?
A. Well, I did not look in our files about if we have a

file on my -- either organization in terms of when I was on their boards and that stuff. I did not look for that. That didn't seem relevant to the focus of the deposition.

Q. Okay. And did you look through any of your old emails?

A. This was before a lot of emails. I mean, we're talking '04, '05, '06, '07.

Did we have emails then?

Q. We did.

A. Okay. Maybe I didn't have emails then.

Q. Yeah, yeah. Okay.

A. No, I did not.

Q. Okay.

A. Okay.

Q. All right. So it seems as if there might be more documents in your possession, but you didn't conduct an exhaustive search?

MR. JANUSH: Objection.

THE WITNESS: Well, I searched for what I thought I was being asked to search for which was what I have said about the industry, what I've said about the criteria, the guidelines, and so forth.

I didn't see any kind of request for documents for my many years of participation in

those organizations.

BY MS. HARTMAN:

Q. Okay. And do you know anything about the lawsuit at issue in this case?

A. I know very little about the lawsuit. I know about -- I know a little bit about it. I don't even know if we're talking about the same lawsuit that was covered by 60 Minutes a couple weeks ago. And so all I know is that there is a lawsuit. I know essentially what it's about, but I don't know a lot of those details.

And, honestly, with all due respect to the plaintiffs' counsel, I'm not even sure I know where that -- they fit in the bigger picture of what I know is a national lawsuit. I mean, it's not something that I'm going to attend to.

Q. All right. Well, thank you for your time today, Doctor.

A. That's all right.

EXAMINATION BY MR. GABEL:

Q. You're not finished, though. I just have a few questions.

A. That's all right.

Q. It will be brief and to the point.

The attempts to lessen the regulation

around prescriptions of opioids that was it Doctor -- well, Professor June Dahl and David Jorensen did at the University of Wisconsin, do you remember about what time that was, what year? And a general --

MS. VICARI: Objection to form.

BY MR. GABEL:

Q. A general ballpark is fine.

A. I'm going to say somewhere before 2010 and maybe between 2005 and 2010. I'm guessing a bit because this stuff was going on for years. There was a lot of early work.

There was a lot of advocacy that I supported in terms of, I mean, when Doctor Portnoy and others, Kathy Foley took the position that we should be more humane about end-of-life and cancer pain, I was right there. I was a pain doctor. I believed in that. It was when things got out of hand in my view that I shifted positions and so forth.

So I think that it was after -- it was around 2004, 2005. I think it spanned several years actually.

Q. Okay. At one point you characterized that twenty years ago, opioids were shamefully underprescribed?

A. Maybe longer now because years have passed.
Q. Okay.
A. I wrote this in 2010. So maybe it's thirty years ago, so --
Q. Okay.
A. Not now because we're sitting here now.
Q. At one point they were underprescribed in your viewpoint?
A. I certainly think that in many cases they were underprescribed.
Q. Okay. And you were not in favor of those overly restrictive impediments, is that right?
MR. JANUSH: Objection.
THE WITNESS: Ask that again.
BY MR. GABEL:
Q. You weren't in favor of those overly restrictive measures that caused them to be shamefully underprescribed?
MR. JANUSH: Objection.
THE WITNESS: Well, there are two --
MR. KENNEDY: Object to form.
THE WITNESS: There are two dynamics. One dynamic was fail to respect the devastating impact of pain, and parallelling that was that a doctor would be at risk if they chose to prescribe

opioids.

To some extent that's good unless that doctor is very well informed, if it's a very special need patient, in which case that would be appropriate care given all the other qualifiers that I put into the testimony today.

So I don't particularly like too many restrictions, but there has to be proper education and there has to be proper credentialing.

BY MR. GABEL:

Q. At the end of the day do you believe it's the physician's responsibility to get it right when it comes to opioid prescription for patients?

MR. JANUSH: Objection.

THE WITNESS: Unless the physician or the physician groups have demonstrated that they can't be trusted with that decision.

I believe that they need to be educated properly and that education has to be balanced, and then I would like to leave it up to the physicians for the most part. Some regulation is good in everything, but there's a limit in my view.

BY MR. GABEL:

Q. But the front lines would be the physicians?

MR. JANUSH: Objection.

THE WITNESS: When you say front lines, would you explain that?

BY MR. GABEL:

Q. Of prescribing opioids. In your speech that you gave, the debate that you gave with the lengthy eighteen-page summary, it says, quote: Whether to prescribe and what and how should depend upon physician judgment and experience.

A. Yes.

Q. Do you agree with that statement?

A. I do agree with that with the qualifier that there has to be credentialing and knowledge by that physician. It can't be any -- listen, there are things in medicine that I don't know anything about, and I've been a physician for fifty years. So you wouldn't want to trust me with something like that, you know, if I don't know anything about it.

That was the whole point. And it wasn't inditing every primary care doctor, but the generalization that I was reacting to was that any doctor at any time and place with any level of education could prescribe to any patient who said I hurt, and that was an attitude in my view.

Q. Do you believe that physicians have to police themselves?

A. Yes.
Q. And if a physician does decide that it's appropriate to prescribe opioids and they give a prescription to their patient, would you expect a pharmacy to fill that prescription?
MR. JANUSH: Objection.
THE WITNESS: Yes, unless there is a dire reason why not. I mean, every doctor can make a mistake, even the best of us, and sometimes second brain thinking about it comes up with something that would alter.
And what I would hope is the pharmacy would call that doctor up and respectfully, you know, say, Doctor, did you realize that this patient is getting this drug from someone else or do you realize the person is on this drug from another doctor and that would be a bad -- that would be contraindicated. That's a good way to help safe, safeguard people, patients. So I believe that.
BY MR. GABEL:
Q. Would a pharmacist have more or less information than a physician? Is it true that typically a physician would have more information about the patient, their history?
MR. JANUSH: Objection.

THE WITNESS: That's a very complicated question because the information may be different. The pharmacist would not have the clinical experience and judgment about this patient's needs and the full history of that patient, but what the pharmacist would have would be a much more encyclopedic set of lists on that drug and the drug interactions with other drugs which get very complicated.

I've spoken to major conventions of pharmacists, and the best and safest care is when cooperating pharmacists and cooperating physicians work together to protect patients. So it's not that they have the same set of knowledge. They know different things.

BY MR. GABEL:

Q. Have you ever had a pharmacist deny a prescription that you have written?

A. Yes.

Q. Okay. And what was the reason for that?

MR. JANUSH: Objection.

THE WITNESS: Well, I can only remember one or two, and in both cases, they did not understand some of the reasons why you give certain drugs.

One was a very esoteric drug called phenelzine or Nardil which is a very complicated antidepressant that is a very excellent drug for very advanced headache cases but has a lot of bad interactions with other drugs. So patients have to be educated.

And when this pharmacy saw the word Nardil, the pharmacist freaked out and said I'm not filling that prescription, this drug could kill you. Well, yeah, yeah, maybe, if you took it with all the other wrong medicines. So that's the kind of interaction I've had.

Most of the pharmacy -- right now what's happening is the pharmacists are looking at computer lists and/or lists from the insurance companies, and their, their decision-making is sometimes altered by that.

BY MR. GABEL:

Q. If a pharmacist refuses to fill a script from a doctor, could it have an adverse impact on the patient?

MR. JANUSH: Objection.

THE WITNESS: Yeah, it could, and I think that both -- I think the medical profession needs to be very tolerant of a respectful call from a

pharmacist that has a constructive dialogue over the issues, and I think that's good care, and I think both sides are faulted, can be faulted for not having good dialogue.

BY MR. GABEL:

Q. We talked about the opioid industry funding some of these societies, funding studies, whatever it may be, and I want to make sure. I represent Walmart. So I just want to make sure we're not --

A. Walmart?

Q. Walmart, yeah.

A. Yes, I've heard of Walmart.

Q. The chain retailer. You've heard of them. And I want to make sure we're not painting with too broad of a brushstroke.

Are you aware of Walmart ever funding APS or AAPM?

A. No.

Q. Are you aware of them funding any society, any medical society whatsoever?

A. No, none.

Q. Are you aware of them having anything to do with the 2009 Opioid Treatment Guidelines?

A. No.

Q. Are you aware of them having anything to do with the

advocacy undertaken by the professors from the University of Wisconsin?

A. No.

Q. Are you aware of any attempts by Walmart or anyone at Walmart to have any influence over the medical profession?

A. No. I can't even remember a discussion with a Walmart pharmacist. So, no, I don't.

Q. Any awareness of any controls that Walmart employs in its dispensing of pharmaceuticals, in particular opioids?

A. No, because we prescribe so few of them now here at this center that I don't -- I'm not aware, I may not be aware of all the interactions we have with pharmacists, but I'm not aware of any personally.

Q. In your 2008 letter, let me see, it's Exhibit 2 or 3. Let me check. It's Exhibit 3. At the end you say: With respect to the risks associated with opioids, you say the media knows it. Government and regulatory agencies know it.

What's your basis for the government -- the statement that the government knows it?

A. Which letter was that?

Q. It's Exhibit 3. It's the one that you wrote on July 1st, 2008, to the --

A. Yes, the resignation letter.
Q. Correct.
A. Well, I was -- as I mentioned to you and we spoke earlier about my Pain Care Coalition responsibility, I was chair of that coalition, and as a result of that, that was a Washington-based coalition, and we personally met with the different -- with various different, in fact, I testified in front of Congress at one point.

And so I know that some of the congresspeople were aware of the issue, and I had a personal relationship, I should say personal professional relationship with Doctor or with Congressman Rogers, and I know that he was acutely aware of this problem. So that was my reference point.

Q. You mentioned you testified before Congress?
A. I did at some point.
Q. Which committee was it, do you remember?
A. I think it was energy, and what's the other, energy, and I can't remember the last name in the title. Energy, it was the one that was writing -- at that point writing the pain, the Pain Care Law.
Q. Okay. The one that you helped author?
A. Yes, I did. I wrote the first draft with

Congressman Rogers.

Q. Okay. And did that have anything to do with opioids at the time?

A. We didn't really get into the opioid issues in that piece of legislation. It was meant to establish the legitimacy of the pain problem and to give credence, congressional credence, to this public health problem called pain.

I mean, there may have been something in there. I don't remember. There were so many iterations of that law before it got passed by the House, then the Senate, even then signed into law. So --

Q. How many times have you been deposed before today?

A. Never this long. You know, I should count up. I've been being deposed as an expert witness or a treating physician for head injury, I do head injury.

Q. Sure.

A. I'm an expert witness in malpractice claims, mostly on the defense side. Some, some when I think it's an egregious act on the plaintiff's side.

In answer to your question, thirty-five, forty times, maybe more. I've got a long career, so I've got to be careful when you ask that kind of

question.

Q. Been around a lot of lawyers, probably more than you like.

A. I've been around a long time, I've been around a long time.

Q. Any time that you were deposed, did it have to do with the subject of opioids?

A. I don't recall that. That's an interesting question. I don't, I don't recall that it ever had anything to do with opioids. If you know otherwise, tell me, because I can't remember. Okay. I'm just saying I don't remember it.

Q. Okay. Okay. That is all I have. Thank you for your time.

A. You're welcome.

MR. JANUSH: Plaintiffs do not have any further questions.

THE WITNESS: Okay.

MS. HARTMAN: Thank you for your time.

THE VIDEOGRAPHER: This concludes the deposition, and we're going off the record at 5:47 p.m.

(Deposition concluded at 5:47 p.m.)

STATE OF MICHIGAN)
)SS.
COUNTY OF LIVINGSTON)

CERTIFICATE OF NOTARY PUBLIC

I certify that this transcript is a complete, true, and correct record of the testimony of the deponent to the best of my ability taken on Friday, January 11, 2019.

I also certify that prior to taking this deposition, the witness was duly sworn by me to tell the truth.

I also certify that I am not a relative or employee of a party, or a relative or employee of an attorney for a party, have a contract with a party, or am financially interested in the action.

_____

Cheryl McDowell, CSR-2662, RPR
Notary Public, Livingston County
State of Michigan
Commission Expires September 13, 2019